1. DEVICE DESCRIPTION

EGIS Colorectal/Pyloric stent is a single use medical device and self-expanding, flexible, nitinol (nikel-titanium alloy) stent that expands to its present diameter upon exposure to body temperature. It is a flexible, fine mesh tubular prosthesis. EGIS Colorectal/Pyloric Stents are available in diameters from 18 to 30mm(Colorectal)/ 16 to 24mm(pyloric) and lengths between 40 and 140mm.

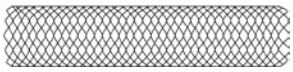
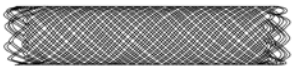
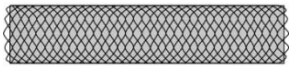
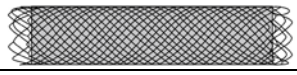
Model Name	Description	Number of Markers (EA)		
		Left End	Middle	Right End
Single Bare Stent		4	2	4
Double Bare Stent		3	2	3
Single Covered Stent (Silicone Type)		7	0	7
Double Covered Stent (Silicone Type)		4	2	4

Figure 1. Stent Configurations

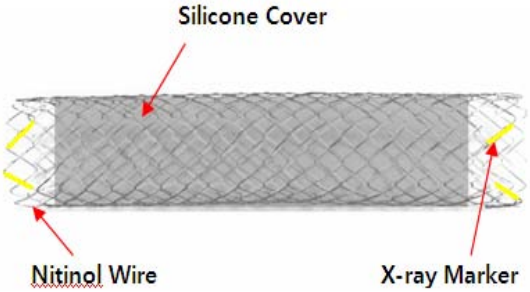
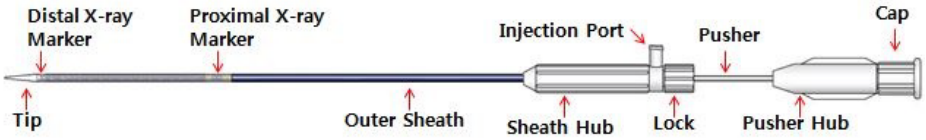


Figure 2. Stent

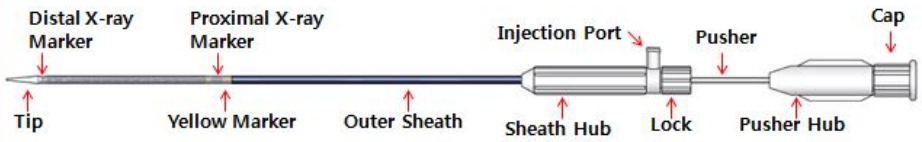
The Stent is loaded in an introducer system and upon deployment the stent imparts an outward radial force on the luminal surface of colorectal/pylorus to establish patency.

[OTW Method]



80, 150cm(Colorectal) 120cm(Pyloric) usable length of introducer system

[TTS Method]



220cm(Colorectal) 180cm(Pyloric) usable length of introducer system

Figure 3. Introducer System

2. SUPPLIED CONDITION

Sterile: EGIS Colorectal/Pyloric 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 device is indicated for the palliative treatment of colonic strictures caused by malignant neoplasm and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures. (Colorectal)
The device is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms. (Pyloric)

4. CONTRAINDICATIONS

Contraindications for the EGIS Colorectal/Pyloric Stent include, but may not be limited to:

- Location of the bowel obstruction/stricture out of that defined by this document
- Suspected or impending perforation
- Severe ascites
- Peritoneal abscess
- Severe coagulopathy
- Enteral ischemia
- 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.
- Evaluate the position of the stenosis by means of plain radiography of the abdomen and enema examination with barium or water-soluble contrast medium in order to make sure that the stenosis is located in the anatomical region which may be accessed by the introducer system
- The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies.

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.

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 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 Colorectal/Pyloric 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.
- 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 Colorectal/Pyloric Stent may include, but are not limited to:

- Stent migration
- Bowel perforation
- Worsening of mild rectal bleeding which has already been presented before the implantation
- Plan stent misplacement or inadequate expansion
- Death

- Stent occlusion
- Foreign body sensation
- Stent occlusion due to tumor ingrowth through stent
- Stent occlusion due to tumor over growth around ends of stent
- Infection
- Fever
- Food impaction

8. DIRECTIONS FOR USE

8.1 Visualization of stricture

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

8.2 Stent Size Determinations

a) Measure the length of the targeted stricture.
b) Select a stent longer than the measured length of the stricture enough to cover both ends of the lesion by about 20 to 40mm.
c) 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)
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
9cm~10cm	12cm	10cm	12cm

Table 1. Stent Information

8.3 Stent Deployment Preparations

The EGIS Colorectal/Pyloric 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 maneuvered until the wire traverses the obstructed area.

A. Fluoroscopic Procedure

a) Under the fluoroscopy, insert a guidewire across the stricture to where the stent introducer system will be placed over it.
b) Advance the introducer system over the guidewire through the stricture.
c) 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

a) Insert an endoscopy to the level of the obstruction.
b) 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.
c) Advance the introducer system over the guidewire through the target stricture.
d) 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.

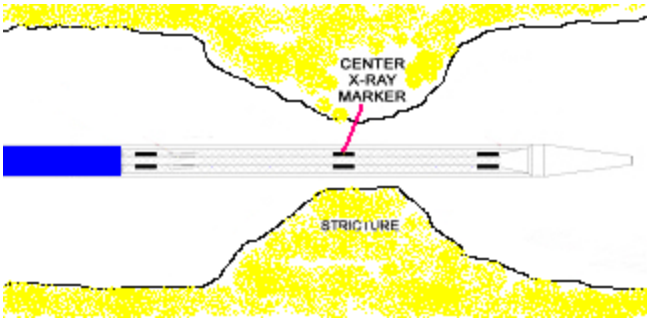


Figure 4. Stent Deployment Procedure

8.4 Stent Deployment Procedures

a) Under the fluoroscopy and / or endoscopy, position the introducer system exactly to the center of the targeted stricture.
b) 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.
c) When the center X-ray marker reaches the center of targeted stricture, the stent can be deployed at any time. (See figure 4,5)

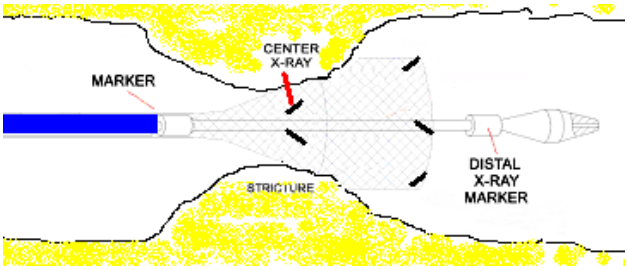


Figure 5. Stent during Deployment

8.5 After Stent Deployment

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

9. POST PROCEDURE

a) Assess the size and structure of the stent lumen. A stent may require up to 1 to 3 days to fully expand.
b) Physician's experience and discretion can determine the appropriate drug regimen for each patient.
c) After implantation, patient should have soft diet.
d) 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

EC REP	Authorized Representative in the Europe
10℃ 40℃	Temperature Limitation
	Consult Instructions For Use
	Manufacturer
REF	Catalog No.
STERILE EO	Sterilized Using Ethylene Oxide
	Attention, Consult Instructions For Use
	Use by(Expiration Date)
SN	Serial No.
	Do Not Reuse
	Date of Manufacture

CE
0120

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