1. DEVICE DESCRIPTION

EGIS Esophageal stent is a single use medical device and a 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 Esophageal Stents are available in diameters from 16 to 20mm and lengths between 40 and 120mm. (But, Double Covered Stent is available lengths between 60 and 120mm) And, Partial type is available in diameters from 18 to 20mm and lengths between 40 and 120mm.

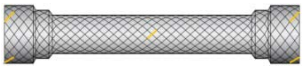
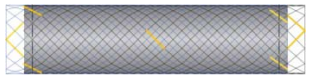
Model Name	Description	Number of Markers (EA)		
		Left End	Middle	Right End
Bare Stent		3	2	3
Covered Stent (e-PTFE Type)		3	2	3
Covered Stent (Silicone Type)		3	2	3
Covered Stent (e-PTFE Anti-Reflux Type)		3	2	3
Covered Stent (Silicone Anti-Reflux Type)		3	2	3
Partial Covered Stent (e-PTFE type)		3	2	3
Partial Covered Stent (Silicone type)		3	2	3
Double Covered Stent (Silicone type)		4	2	4

Figure 1. Stent Configurations

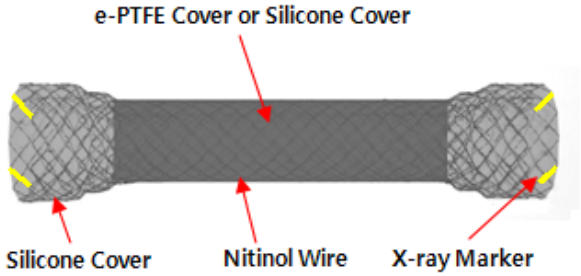


Figure 2. Stent

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

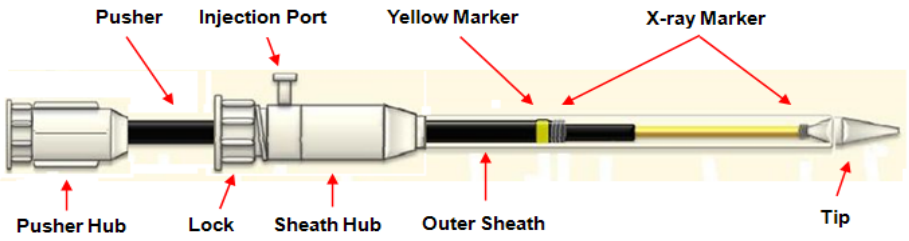


Figure 3. Introducer System

2. SUPPLIED CONDITION

Sterile: EGIS Esophageal 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 Esophageal Stent is intended for re-establishing luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant and/or benign stricture.

4. CONTRAINDICATIONS

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

- Serious blood clotting disorders
- Placement in necrotic chronically bleeding tumors
- Placement in polypoid lesions
- Extremely narrow and rigid strictures that cannot be dilated to allow passage of the introducer system
- Esophageal perforation or fistula without stenose, which can contribute to improper anchoring
- Patients, with whom endoscopic techniques cannot be performed and/or are contraindicated
- 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, coagulopathies, or in patients with radiation colitis or proctitis.

Device Warnings:

- EGIS Esophageal Cover Type Stents may be removed after physician's clinical assessment of the stent and stricture conditions. Caution should be exercised in deciding if the stent should be removed.
- EGIS Esophageal Cover Type Stents cannot be removed in the cases of tumor in-growth / over-growth / occlusion of the stent lumen.
- EGIS Esophageal Covered Stent may be repositioned immediately after deployment.
- Do not reposition the stent by grasping the stent's cover part.
- Care should be taken when removing the introducer system and guide wire immediately after stent deployment since this may result in stent dislodgement if the stent has not been adequately deployed.
- Care should be taken when performing dilation after the stent has been deployed as this may result in perforation, bleeding, stent dislodgement or stent migration.
- Chemo-radiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration.

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 Esophageal 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.
- The stent and its introducer system must not be used except for the indications identified above.
- 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 the device 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.
- 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 Esophageal Stent may include, but are not limited to:

- Stent migration
- Perforation
- Bleeding
- Aspiration
- Pain/Foreign body sensation
- Occlusion due to lesion growth
- Obstruction related to food volume
- Infection
- Reflux
- Esophagitis
- Esophageal ulceration
- Edema
- Fever
- Fistula formation outside of normal disease progression
- Death with cause outside of normal disease progression

8. DIRECTIONS FOR USE

8.1 Visualization of stricture

a) Carefully examine both the proximal and distal segment of stricture endoscopically and/ or fluoroscopically.
b) The internal luminal diameter should be measured exactly with fluoroscope.

8.2 Stent Size Determinations

a) Measure the length of the targeted stricture.
b) The stent should be selected to exceed the length of the stricture by at least 1cm on both ends (total recommended over-sizing 20-40 mm)
c) The unconstrained diameter of the stent should exceed the internal lumen of the stricture by at least 3-4mm to achieve secure fixation

Bare Stent		Covered Stent (Silicone / e-PTFE / Anti / Partial / Double)	
Stricture length (cm)	Stent length (cm)	Stricture length (cm)	Stent length (cm)
Less than 3cm	4cm	Less than 4cm	4cm
3cm~5cm	6cm	4cm~5cm	6cm
5cm~7cm	8cm	6cm~7cm	8cm
7cm~8cm	10cm	8cm~9cm	10cm
8cm~10cm	12cm	10cm	12cm

Table 1. Stent Information

8.3 Stent Deployment Preparations

The EGIS Esophageal 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) Under the fluoroscopy/endoscopy, insert a guidewire across the stricture to where the stent introducer system will be placed over it.
b) Check that the outer sheath of the introducer system is safely locked by rotating the locking nut in clockwise direction.

c) Under the fluoroscope and/or endoscopy guidance, position the introducer system to the center of the targeted stricture. (Based on center X-ray marker) (Fig. 4)

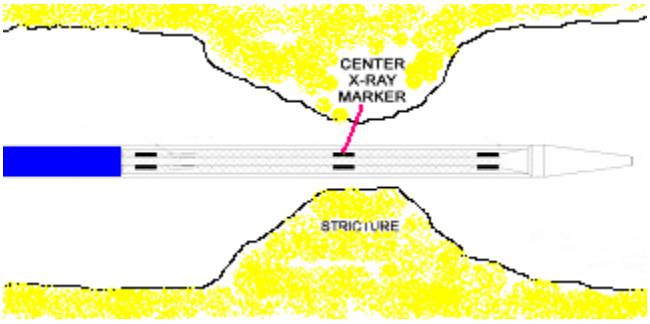


Figure 4. Stent Deployment Procedure

8.4 Stent Deployment Procedures

a) Once the introducer system is in the correct position for deployment, unlock the restraining sheath by turning the locking nut counter-clockwise

b) While maintaining correct positioning of the introducer system, start deploying the stent by withdrawing the outer sheath, while holding the pusher shaft in a fixed position

c) Once deployment has begun, continue to check for correct position. Minor adjustments can be made if only a small amount of the stent has been deployed.

d) Once the stent has been completely deployed, remove the introducer system over the guide wire

e) Radial force of the stent increases with body temperature

f) In case of miss positioning of stent, it may be removed with a forceps or a snare immediately after deployment. (This should be done prior to any dilatation with a balloon)

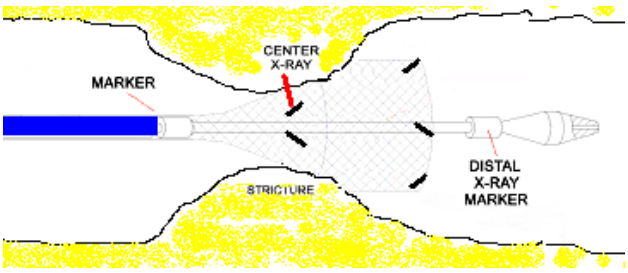


Figure 5. Stent during Deployment

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

S&G Biotech Inc.,
Jungang Induspia #304, 449
Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do,
462-713 Korea
Tel. +82.31.748.6625
Fax. +82-31-748-6620
Email: sng@sngbio.com

EC REP **Medical Device Safety Service GmbH**
Schiffgraben 41
30175 Hannover
Germany
Tel. +49 511 6262 8630
Fax. +49 511 6262 8633
Website: www.mdss.com

Doc. No: MEN-02-01 (Rev.1)
Date: Jan. 22nd, 2015