# INSTRUCTION For Use EGIS ESOPHAGEAL STENT

CE 0120

## 1. Product Information

EGIS Esophageal Stents are medical devices which must only be used by qualified physicians appropriately trained in interventional procedures:
The physician placing the stent must be familiar with the device and have read and understood the instructions for use.

## 2. Product type

The EGIS Esophageal Stent is available in 4 different configurations: Bare, e-PTFE Cover, Silicone Cover and Anti-Reflux. The stents are supplied preloaded in a delivery system, they are sterilized and ready to use. The EGIS Esophageal Stents are self-expanding stents woven from a biocompatible nickel/titanium alloy (Nitinol) wire.

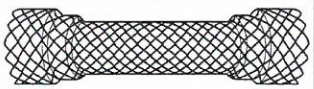
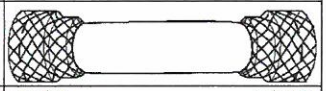
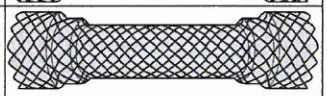
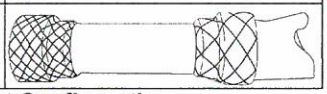
| Model | Description |
|---|---|
| Bare Stent |  |
| Cover Stent (e-PTFE Type) |  |
| Cover Stent (Silicone Type) |  |
| Cover Stent (Anti-Reflux Type) |  |

**Figure 1. Stent Configurations**

## 3. Product description

The EGIS Esophageal System consists of a self-expanding metal stent and the introducer system. EGIS Esophageal Stents are extremely flexible with superior conformability to the bowel and its flexures.

- Due to the "knitted" construction no straightening forces are transmitted onto the bowel wall reducing the risk of displacement and perforation.
- EGIS Esophageal Stents have 8 tubular radiopaque markers in three sets: 3 at each stent end and 2 in the center
- Egis Esophageal Stents are available in diameters from 16 to 20mm and lengths between 40 and 120mm.
- Stents are delivered ready to use in a delivery system. It consists of an outer sheath and a central pusher, which maintains stent position while the sheath is withdrawn.
- The sheath has a handle with a locking nut at the proximal end.
- The distal end of the delivery system is formed by a tapered tip, which facilitates insertion even through tight strictures.
- The stent is compressed against the pusher by the sheath; radiopaque x-ray markers on the pusher allow accurate stent positioning

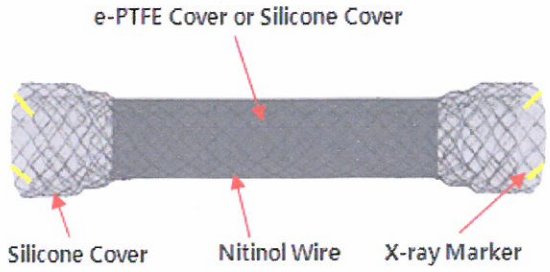



**Figure 2. Stent**

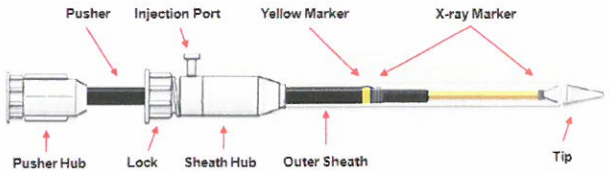



**Figure 3. Introducer**

## 4. Indication for Use

The EGIS Esophageal Stent is intended for re-establishing luminal patency in Esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

## 5. Cautions

- Read the entire directions for use thoroughly before using this device. It should only be used by or under the supervision of physicians thoroughly trained in the placement of Esophageal stents. A thorough understanding of the techniques, principles, clinical applications and risk associated with this procedure is necessary before using the device.
- The stent must only be used by physicians with appropriate training.
- The stent and its delivery system must not be used except for the indications identified above.
- Visually inspect the system for any sign of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this precaution may result in patient injury.
- The EGIS Esophageal Stent is supplied sterile. Do not use any unit if its package is opened or damaged.
- The device must not be used after the "use by" date.
- The EGIS Esophageal Stent is intended for single use only. Do not resterilized and/or reuse the device.
- Do not attempt to reload deployed stents onto the introducer system.
- Use of fluoroscopy is recommended. Not using fluoroscopy increases the risk of stent misplacement.
- The EGIS Esophageal Stent is verified to be MRI safe at field strengths up to 2.0 Tesla

## 6. Contraindications

EGIS Esophageal Stent should not be placed in the following circumstances

- Benign Esophageal strictures. (e.g. anastomotic, ischemic)
- Suspected or impending perforation.
- Intra-abdominal abscess.
- Strictures that do not allow passage of a guide wire.
- Any use other than those specifically outlined under

indications for use.

- Patients for whom fluoroscopically techniques are contraindicated.
- Proven systemic allergic reactions to any of the components. (contact dermatitis to nickel has not been shown to predispose to systemic hypersensitivity)
- Uncorrected severe bleeding disorders.

**7. Potential complications**

Potential complications associated with the use of EGIS Esophageal Stent may include, but are not limited to:

*Procedural Complications*

- Bleeding
- Perforation/peritonitis
- Stent misplacement or inadequate expansion
- Persistent Pain
- Death
- Infection
- Hypotension
- Respiratory depression or arrest
- Cardiac arrhythmia or arrest
- Aspiration

*Post Stent Placement Complications*

- Persistent pain
- Severe pain
- Bleeding / Mucosal ulceration / Hemorrhage
- Foreign body sensation
- Symptoms of tenesmus or urgency/incontinence
- Diarrhea / Constipation
- Fecal impaction
- Stent migration
- Stent occlusion due to tumor in-growth into stent
- Stent occlusion due to tumor overgrowth around stent ends
- Perforation
- Peritonitis
- Septicemia
- Fever
- Death
- Esophagitis
- Airway Compressions
- Esophagus Compression
- Haematemesis
- Pneumonias
- Acute angulations
- Esophageal bronchial fistula
- Recurrent dysphasia
- Sputum retention

**8. Warnings**

- The device should be used with caution and only after careful consideration in patients with prolonged bleeding times, coagulopathies, or in patients with radiation colitis or proctitis.
- Partially deployed stents cannot be "recaptured" or "resheathed" into the delivery system.
- 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.
- The stent is not designed for repositioning or removal after deployment.
- Chemo-radiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration.
- There is no published evidence that contact dermatitis to nickel is a risk factor for systemic allergic reactions. However, all patients with established nickel hypersensitivity should be considered for immunology / dermatology assessment prior to stenting.
- To minimize pain and tenesmus, the proximal stent end should be placed 2 cm above the anal canal or 6 cm from the anus.
- Do not expose the introducer system to organic solvents. (e.g. Alcohol)
- Do not use with fat soluble contrast media (eg Lipiodol or Ethiodol)

**9. Instructions for use**

**a. Equipment required**

- Therapeutic endoscope (with a working channel size of 3.8mm or greater) and / or x-ray screening unit (fluoroscopy)
- Stiff 0.035 inch (0.89mm) guide wires
- Angiographic / endoscopic catheter
- Radiographic contrast
  (Dilatation balloon and inflation set)

**b. Visualization of stricture**

- Both the proximal and distal end of the stricture need to be demonstrated. Fluoroscopy allows more accurate assessment of the internal lumen and length of the stricture
- Pre-dilatation of the stricture should only be performed if the stent delivery system cannot be passed

**c. Determination of stent size (please refer to table of recommended standard sizes.)**

- Measure the length of the target stricture
- The stent should be selected to exceed the length of the stricture by at least 1cm on either end (total recommended over-sizing 20-40 mm)
- The unconstrained diameter of the stent should exceed the internal lumen of the stricture by at least 3-4mm to achieve secure fixation
-

| Bare | | Cover (Silicone / e-PTFE / Anti) | |
|---|---|---|---|
| **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**

**d. Stent placement**

The EGIS Esophageal Stent can be placed with the aid of fluoroscopy, or under direct visualization alongside an endoscope or the combination of both.

**Radiological placement**

- Advance catheter and guidewire to the lower end of the stricture
- Outline the stricture by injection of water-soluble contrast.
- Place a sufficiently long guidewire well across the stricture. There must be sufficient length outside the patient to match the length of the delivery system
  The use of a stiff guidewire is recommended
- Remove the stylet from the distal end of the delivery system and flush the wire channel as well as the inner lumen of the introducer sheath through the injection port
- Check that the outer sheath of the delivery system is safely locked onto the shaft by rotating the locking nut in a clockwise direction
- Insert the delivery system over the guidewire and position it with the middle markers at the centre point of the tumor (Fig. 4)

**e. Stent deployment**

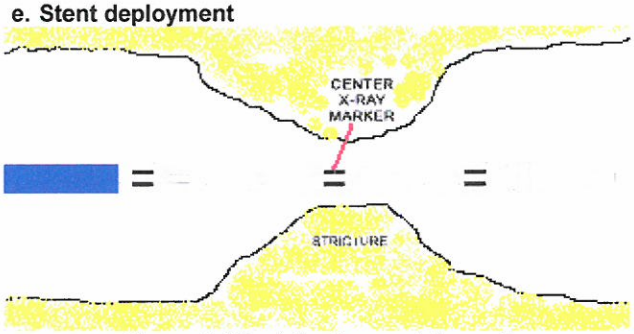



**Figure 4. Stent Deployment Procedure**

- Once correct positioning of the delivery system has been confirmed, unlock the restraining sheath by turning the locking nut counter-clockwise
- While maintaining correct positioning of the delivery system, begin stent deployment by withdrawing the outer sheath, while holding the pusher shaft in a fixed position
- Once deployment has begun, continue to check for correct positioning. Minor adjustments can be made if only a small amount of the stent has been deployed
- Once the stent has been completely deployed remove the introducer system over the guidewire
- Radial force of the stent increases with warming to body temperature and after release the stent will continue to expand slowly
- If the stent does not expand at least 50% of the nominal diameter balloon dilatation can be considered. However the stent should be given at least 3-5 minutes to allow for further expansion
- In case of poor positioning the stent may be removed with forceps or a snare immediately after deployment. This should be done prior to any dilatation with a balloon

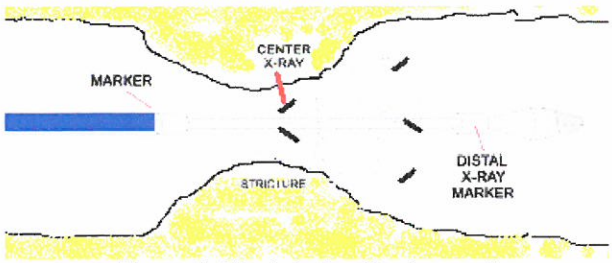



**Figure 5. Stent during Deployment**

⚠ **CAUTION** Do not advance or withdraw the pusher handle with the stent partially deployed. The pusher must be securely immobilized and the stent deployed by withdrawing of the sheath. Inadvertent movement of the pusher may cause misalignment of the stent and possible intestinal wall damage.

⚠ **CAUTION** In case of poor positioning, if it is necessary to remove the stent, using a forceps or snare.

**10. Post procedure**

- The stent may require several days to expand fully. The success of the procedure should be judged on the resolution of the patient's symptoms and not on the appearance of the stent on imaging alone
- No specific medication is recommended, but consideration should be given to the administration of stool softening laxatives
- The patient should be observed for signs of complications for several hours. In particular continued abdominal pain should prompt further investigations.

**11. Storage: Store the device in a cool and dry area.**

⚠ **CAUTION** Federal law restricts this device to sale by or on the order of a physician.

**Reuse Precaution Statement**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged, please call your S&G Biotech INC. representative.

For single patient use only. Do not reuse, reprocess or resterilized. Reuse, reprocessing or resterilization 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

**WARRANTY**

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warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

**Symbol**

| | |
|---|---|
| EC REP | **Authorized representative in the Europe** |
|  | **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** |

**Manufactured by S&G Biotech INC.**
SK Apt. Factory #301,
223-28 Sangdaewon-Dong Jungwon-Cu,
Seongnam-Si, Gyeonggi-do, 462-705 Republic of Korea
Tel : +82(31)748-6625 Fax : +82(31)748-6620
E-mail : sngbio@sngbio.com

EC REP **DongBang Acuprime**
1 Forrest Units.
Hennock Road East
Marsh Barton
Exeter
U.K EX2 8RU
Tel. +44 1392 829500
Fax. +44 1392 823232
Website : www.acuprime.com