Patient Information Leaflet
(Esophageal Stent with Delivery system)

This leaflet has been written to help you understand stent. The doctor doing the procedure will discuss these in detail with you before they carry out the procedure.

* **PRODUCT** Information

Product Name	**Esophageal Stent with Delivery System**	
Brand Name	HANAROSTENT®	
Manufacturer	M.I.Tech Co., Ltd.	
Model Name	Non-covered Stent	HANAROSTENT® Esophagus Lasso (NNN)
	Covered Stent	CHOOSTENT® Esophagus (CCC) CHOOSTENT® Esophagus Asymmetric (CCC) CHOOSTENT® Esophagus Upper (CCC) CHOOSTENT® Esophagus Upper ST (CCC) CHOOSTENT® Esophagus (NCN) CHOOSTENT® Esophagus ST (CCN) CHOOSTENT® Esophagus ST (CCC) HANAROSTENT® Esophagus (CCC) HANAROSTENT® Esophagus Asymmetric (CCC) HANAROSTENT® Esophagus (NCN) HANAROSTENT® Esophagus Upper (CCC) HANAROSTENT® Esophagus Upper ST (CCC) HANAROSTENT® Esophagus BS (CCC) HANAROSTENT® Esophagus BS (NCN) HANAROSTENT® Esophagus Flap BS (CCC) HANAROSTENT® Esophagus Skidproof (CCC) CHOOSTENT® Esophagus Valve (CCC) CHOOSTENT® Esophagus Valve (CCN) CHOOSTENT® Esophagus Valve ST (CCN) HANAROSTENT® Esophagus Valve (CCC) HANAROSTENT® Esophagus Valve (CCN) HANAROSTENT® Esophagus Valve BS (CCC) HANAROSTENT® Esophagus Valve BS (CCN) CHOOSTENT® PROXI™ Esophagus Asymmetric (CCC) HANAROSTENT® PROXI™ Esophagus Asymmetric (CCC) CHOOSTENT® PROXI™ Esophagus Upper (CCC) HANAROSTENT® Esophagus TTS (CCC) HANAROSTENT® Esophagus TTS (NCN) HANAROSTENT® Esophagus Benign BS (CCC) HANAROSTENT® Esophagus Benign BS ST(CCC) HANAROSTENT® Esophagus Bariatric Surgery (CCC) HANAROSTENT® Esophagus Bariatric Surgery ST(CCC) HANAROSTENT® Gastro-Seal™ Esophagus (CCC) HANAROSTENT® Gastro-Seal™ Esophagus ST (CCC) HANAROSTENT® Luso-Cor esophageal stent
Intended use	This device is indicated for maintaining lumen patency of esophageal stricture and/or closing of esophageal fistula caused by malignant and/or benign neoplasm.	
Intended patient Population	Adult patients with esophageal stricture caused and/or esophageal fistula by malignant and/or benign neoplasm	
Expected lifetime	*within 540 days* *※ Since clinical data for patency after expected lifetime have not been verified, after the expected life time has elapsed, consult with your doctor to discuss follow up.*	

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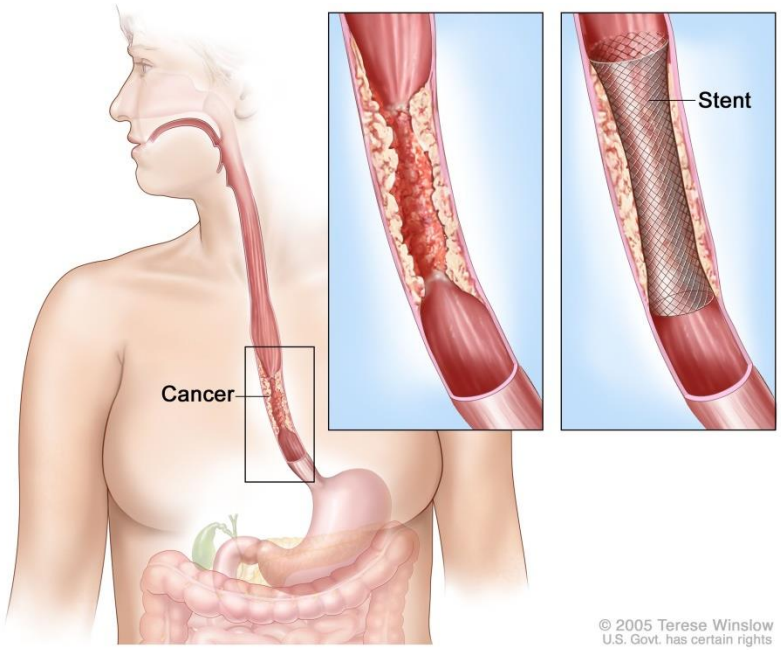
* What is **ESOPHAGEAL STENT**?



A tube placed in the esophagus to keep a blocked area open so the patient can swallow soft food and liquids. Esophageal stents are made of metal mesh, plastic, or silicone, and may be used in the treatment of esophageal cancer.

Your esophagus is the muscular tube connecting the back of your mouth to your stomach. When you swallow, the muscles of your esophagus contract. They propel food into your stomach.

Many health problems can partly block a portion of your esophagus. That can make it hard to swallow. The medical term for this is dysphagia. You might have pain when you swallow or feel like food is getting stuck in your chest. The food might come back up after you swallow. An esophageal stent can help reopen your blocked esophagus and ease symptoms.

The procedure might take place under general anesthesia or conscious sedation. If it takes place under general anesthesia, you will sleep through the procedure and feel no pain. If it takes place under conscious sedation, you will get medicines to make you relaxed and sleepy. The surgeon may numb the area under surgery so that you won't feel much pain.

* Does the stent stop the tumour from growing?
No. The stent prevents the tumour from blocking the digestive system so helps you to eat and drink more normally. It doesn't prevent the tumour from growing.

* What are the risks involved?
Stent insertion is generally safe, but as with most medical treatment, there are some risks.
These include: Some people get pain afterwards. This can be controlled with medicine if necessary.
Occasionally a stent may slip out of position and the procedure will need repeating.

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Serious complications due to a stent insertion are rare. However, some side effects may require emergency treatment.

* **PREPARATION** for the procedure

Arrangements will be made for you to have a blood sample taken. This needs to be within two to three days before the procedure or if needed will be taken on the day of the test in the endoscopy unit. Please don't have anything to eat or drink for at least six hours before the procedure. If there are problems with your stomach emptying, this period may need to be longer but you will be told if this is necessary. You can take any normal medication swallowed with a small amount of water before the stent insertion. If you are diabetic or take warfarin, specific instructions regarding taking your medication will be given. If you are unsure what to do, please ask the procedure takes place at the endoscopy unit. On arrival an endoscopy nurse will meet you and carry out a health-check to make sure it is still safe to carry out the stent insertion on that day. The doctor will discuss with you before carrying out the procedure its intended benefits, risks of serious complications and any alternative treatment with you.

* How can you **CARE FOR YOURSELF**

- Rest when you feel tired. Getting enough sleep will help you recover.
- Avoid activities or exercises that use your belly muscles for 1 week or until your doctor says it is OK. For example, bicycle riding, jogging, weight lifting, or aerobic exercise.
- Don't lift or carry anything heavier than 4.5 kg (10 lb) for 3 days. As you feel ready, do a little more activity each day for the next 7 days after the procedure.
- Follow your doctor's directions for eating after the procedure.
- Drink plenty of fluids (unless your doctor tells you not to).
- If your doctor gave you a prescription medicine for pain, take it as prescribed.
- If you're not taking a prescription pain medicine, ask your doctor if you can take an over-the-counter medicine.
- Your doctor will tell you if and when you can restart your medicines. They will also give you instructions about taking any new medicines.
- If you take aspirin or some other blood thinner, be sure to talk to your doctor. They will tell you if and when to start taking this medicine again. Make sure that you understand exactly what your doctor wants you to do.
- **Follow-up care is a key part of your treatment and safety. Be sure to make and go to all appointments, and call your doctor or nurse call line if you are having problems.**
- **Please bring your patient implant card with you when taking MR imaging.**

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* SIDE EFFECTS

The physician should be informed of any adverse events in patients who have had a stent implanted.

• Bleeding • Pain • Perforation • Infection • Tissue Necrosis • Stent misplacement or migration • Occlusion • Tumor overgrowth • Tumor ingrowth • Fever • Foreign body sensation • Death (other than that due to normal disease progression) • Sepsis • Acute angulations	• Pneumonias • Haematemesis • Tracheal Compressions • Reflux • Rupture • Food bolus impaction (lavage and debridement may be necessary on a periodic basis) • Esophagitis • Dysphagia • Ulcerations • Aspirations • Stent fracture • Mucosal tear • Unsuccessful first removal attempt	• Esophageal avulsion • Stridor requiring endotracheal intubation • Fistula formation • Esophagorespiratory fistula • Impossibility to remove the stent • Dislocation in stomach • Cover breakdown with ingrowth in the mucosa • Aorto and arterioesophageal fistula • Stent erosion • Vomiting or nausea • Leakage

* CONTRAINDICATIONS

- Strictures that cannot be dilated enough to pass the delivery system
- Chronically bleeding tumors, if bleeding is active at the time of placement
- Patients for whom the endoscopic treatments are contraindicated
- Enteral ischemia
- Multiple sites of obstruction
- Standard endoscopy contraindications
- Any use other than those mentioned in Indications for Use
- Allergy to metal (e.g. Nitinol, Nickel, Gold and Titanium)

* Incident notification

Notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the regulatory authorities as below;

- Europe: European commission (https://webgate.training.ec.europa.eu/eudamed-play/landing-page#/)
- Australia: Therapeutic Goods Administration (www.tga.gov.au)
- Manufacturer: M.I.Tech Co., Ltd. (http://www.mitech.co.kr, mitech@mitech.co.kr)

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