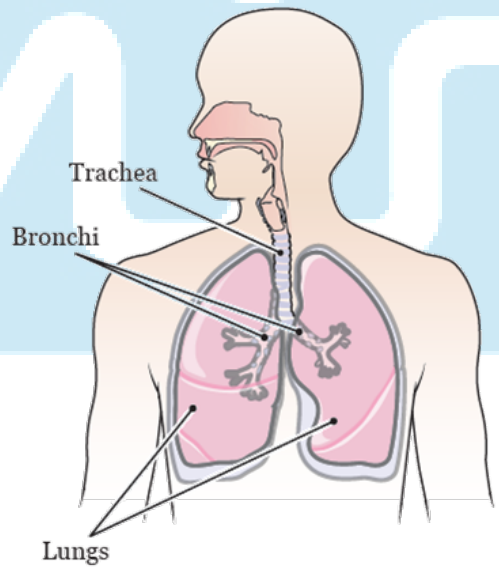
Patient Information Leaflet
(Tracheo/Bronchial Stent with Delivery system)

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	**Tracheo/Bronchial Stent with Delivery System**	
Brand Name	HANAROSTENT®	
Manufacturer	M.I.Tech Co., Ltd.	
Model Name	Covered Stent	HANAROSTENT® Trachea/Bronchium (CCC)
Intended use	This device is indicated for maintaining lumen patency of tracheo/bronchial stricture and/or closing the tracheo-esophageal fistula, caused by malignant neoplasm.	
Intended patient Population	Adult patients who have tracheo/bronchial stricture and/or tracheo-esophageal fistula caused by malignant neoplasm	
Expected lifetime	within 277days ※ 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.	

* What is **TRACHEO/BRONCHIAL STENT**?



The stent can be placed in either your trachea or your bronchi, depending where the narrow area is. Your trachea is the tube that carries air from your nose and mouth into your lungs. Your bronchi are tubes that branch off your trachea and lead to different areas of your lungs.
Stents can be made of different materials, such as metal or silicone. They also come in different sizes and shapes. They can be temporary or permanent. A computed tomography (CT) scan will help your doctor decide which type will most help you.
Your stent will be placed during a procedure called a bronchoscopy. During a bronchoscopy, your doctor will put a flexible camera called a bronchoscope though your nose or mouth, into your trachea or bronchi.

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- Tracheo/Bronchial Stent with Delivery System
  - STENT: It is covered stent with silicone. The stent forms a structure by weaving Nitinol wires into a net shape, and a silicone film is formed on the structure to cover it. In addition, small coils made of gold are placed on the stent to clearly check the position of the stent during or after the procedure. The stent stays in your body to maintain lumen patency.
  - Delivery system: It is used briefly during the procedure to place the stent at the site of the lesion. It is not a component to be implanted into the body, and is made of a polymer material (Polyurethane, Polyether block amide, Polyamide, Polytetrafluoroethylene, polyether ether ketone, etc.) widely used in medical devices.

※ We sterilize the final product with EO gas. And we are validating EO gas residues periodically every year, and safety and effectiveness have been verified.

* 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. If your pain is severe, you should contact doctor or nurse for advice. Occasionally a stent may slip out of position and the procedure will need repeating.
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**

It is important for patients to take certain precautions to ensure the longevity of the stent and minimize the risk of complications.

- 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. If patients do excessive force or pressure physically on the area where the stent has been placed, it may impact the longevity of the stent.

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- Avoid engaging in heavy lifting or strenuous physical activities that could potentially put stress or pressure on the stent, leading to damage or dislodgement. 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. This may include avoiding certain foods or beverages that could potentially irritate the stent or cause blockages, such as spicy or fatty foods.
- 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. Proper medication management may help prevent complications that could affect the lifespan of the stent.
- **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.**

*** MRI SAFETY INFORMATION**

- What should I do if I am undergoing an MRI scan?

This product is MR conditional (MRI: Magnetic Resonance Imaging, a medical imaging technique using magnetic fields). The MRI safety information is described as below.
Please carry the "Patient Implant Card" with you at all times and show it to any medical professional who treats you. The conditions described below ensure your safety as a patient undergoing an MRI scan.

- MRI safety information

A patient with this stent can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.

Non-clinical testing and electromagnetic/thermal modeling demonstrated that the stents are MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode of operation for the MR system)

Under the scan conditions defined, the stents are expected to produce a maximum temperature rise of less than 2˚C after 15-minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the stents extends approximately the stents 6 mm from this implant when imaged using a spin echo pulse sequence and a 3-Tesla MR system.

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*** SIDE EFFECTS**

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

• Dyspnea • Pain • Bleeding • Fever • Rupture • Infection • Halitosis • Accumulation Expectoration • Hemoptysis • Granulation Formation • Tissue Necrosis • Mucoid Impaction • Tracheobronchial perforation and pneumothorax	• Worsening of Fistula • Inflammation • Occlusion • Tumor Overgrowth • Tumor Ingrowth • Mucosal hyperplasia • Stent misplacement or migration • Edema • Erosion • Death (other than that due to normal disease progression)	• Tracheitis • Oxygen desaturation related to sedation or procedural • Aspiration • Pneumoperitoneum • Aphonia • Obstructive atelectasis (even with a well-positioned stent) • Stent fracture • Heart Failure • Hypoxia • Thrombosis • Ischemia

*** 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@mitechglobal.com)

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