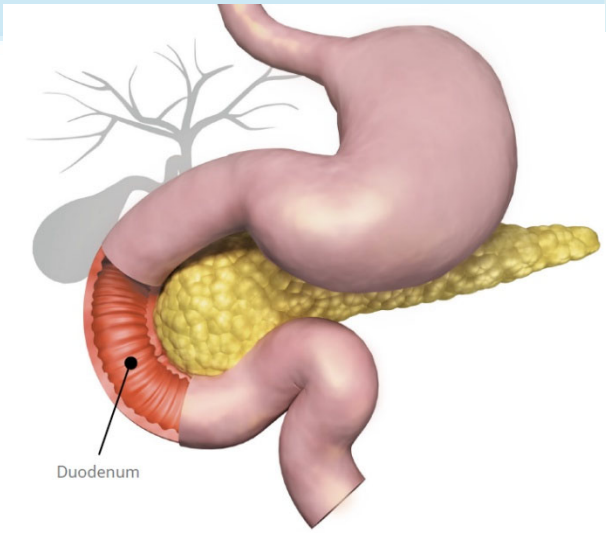
Patient Information Leaflet
(Duodenal/Pyloric Stent with Delivery system)

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	**Duodenal/Pyloric Stent with Delivery System**	
Brand Name	HANAROSTENT®	
Manufacturer	M.I.Tech Co.,Ltd.	
Model Name	Non-covered Stent	HANAROSTENT® Duodenum/Pylorus (NNN) HANAROSTENT® Duodenum/Pylorus Lasso (NNN) HANAROSTENT® Naturfit™ Duodenum/Pylorus (NNN) HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN)
	Covered Stent	HANAROSTENT® Duodenum/Pylorus (NCN) HANAROSTENT® Duodenum/Pylorus Lasso (NCN) HANAROSTENT® Duodenum/Pylorus Kim's Flare (NCN) HANAROSTENT® Duodenum/Pylorus Kim's Flare (CCN) HANAROSTENT® Duodenum/Pylorus ZEUS-T (NCN) HANAROSTENT® TwynLay™ Duodenum/Pylorus (NCN)
Intended use	This device is indicated for the palliative treatment of duodenal/pyloric stricture caused by malignant neoplasm	
Intended patient Population	Adult patients with duodenal/pyloric stricture caused by malignant neoplasm.	
Expected lifetime	within 358 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.	

* What is **DUODENAL/PYLORIC STENT**?



A stent is a small metal mesh tube which is placed in the narrowed or blocked area of your duodenum. The duodenum is the first part of your small bowel, attached to your stomach. The stent is placed

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across the narrowing or blockage and will expand to allow fluid and food to pass through from your stomach more easily. This will help to reduce symptoms such as vomiting and regurgitation.

* 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.
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.

• Pain • Bleeding • Fever • Rupture • Fistula • Pancreatitis • Infection • Jaundice • Perforation • Intraprocedural events • Tissue necrosis • Inflammation	• Occlusion • Tumor ingrowth • Biliary obstruction • Food impaction • Nausea • Tumor overgrowth • Mucosal hyperplasia • Stent misplacement or migration • Edema • Erosion	• Death (other than that due to normal disease progression) • Bowel impaction • Sepsis • Peritonitis • Ulceration • Foreign body sensation • Stent fracture • Vomiting or nausea • Collapse • Aspiration pneumonia • Granulation tissue

*** 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)