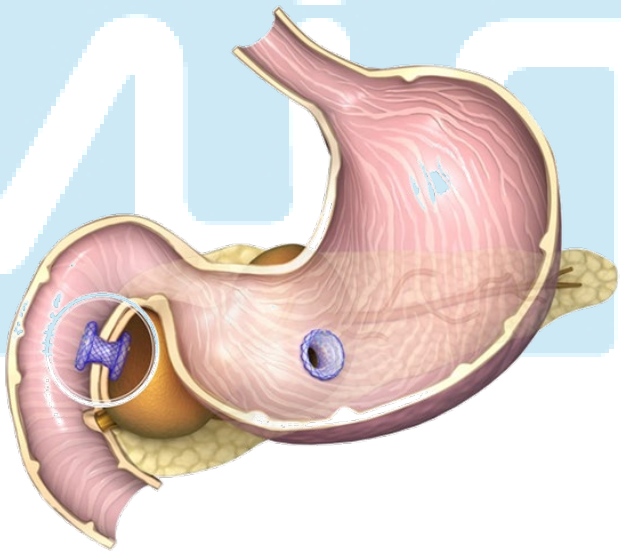
Patient Information Leaflet
(Pancreatic drainage Stent with Delivery system)

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	**Pancreatic drainage stent with Delivery System**
Brand Name	HANAROSTENT®
Manufacturer	M.I.Tech Co.,Ltd.
Model Name	HANAROSTENT® Plumber™
Intended use	This device is indicated for drainage of a pancreatic pseudocyst or a walled off necrosis through a transgastric or transduodenal approach.
Intended patient Population	Adult patients with pancreatic pseudocyst or walled off necrosis caused by pancreatic disease.
Expected lifetime	within 60 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 **PANCREATIC DRAINAGE STENT**?



The Pancreatic drainage stent enables physicians to treat patients endoscopically instead of surgically. The Stent creates an anastomotic conduit between two lumens, enabling blockages and strictures to be bypassed and large fluid collections to be drained.
It have been primarily designed and developed to improve endoscopic treatment outcomes in the management of PFC, particularly walled-off necrosis (WON), and to facilitate better drainage of necrotic contents and minimize the risk of perforation and peritoneal or retroperitoneal leakage.

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- Pancreatic Drainage Stent with Delivery System
  - STENT: It is a 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 drain pancreatic fluid or abscess, and prevent tissue in-growth..
  - 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.

* 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.
- 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 1.3W/kg for the MR system

Under the scan conditions defined, the stents are expected to produce a maximum temperature rise of less than 6˚C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the stents extends approximately the stents 13.7 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.

• Pain • Bleeding • Fever • Infection • Peritonitis • Tissue Necrosis • Jaundice • Cholangitis • Pancreatitis • Anesthesia complications • Tissue ingrowth or overgrowth leading to difficult or a failure to remove stent • Occlusion • Local infection at the implant site • Sepsis (bacterial, endotoxin, or fungal)	• Persistent connection to fluid collection after removal(fistula) • Cardia arrhythmia or arrest • Partial or failed stent expansion, stent collapse • Device failure, including failure to deliver the stent • Stent misplacement or migration • Abscess formation • Aggravated walled off necrosis • Adverse reaction to implant and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation/foreign body reaction)	• Minor or excessive bleeding (requiring intervention) • Leakage of fluid collection or bowel contents/peritonitis • Tissue damage during stent implantation and/or removal • Ulceration or erosion of mucosal or organ wall linings • Pneumoperitoneum • Perforation • Stent fracture including damage of covering membrane • Death • Rupture • Edema

*** CONTRAINDICATIONS**

- All cardiovascular applications.
- Hemodynamic instability
- Severe coagulopathy
- Cystic neoplasms.
- Pseudoaneurysms.
- Duplication cysts.
- Non-inflammatory fluid collections.
- Patients with abnormal coagulation or who require ongoing complete anticoagulation at the time of implantation and post stent placement have an increased possibility of bleeding.
- Patients with altered anatomy that precludes the physician's ability to deliver the stent.
- Patients with intervening gastric varices or vessels within a one centimeter radius of the device needle.
- Allergy to metal (e.g. Nitinol, Nickel, Gold and Titanium).
- All others than indication for use

* 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)