

# Tierrett PEG Kit

## Instructions for use

**Contraindicated to re-use**

### [WARNINGS]

#### <Using method>

- [1] This product is a medical device for endoscopic gastrostomy. Perform the procedure while checking with an endoscope.
  - [There is a risk of damage to the organs and posterior wall of the stomach and accidental puncture.]
- [2] After insertion with an endoscope that the bumper is properly placed in the stomach.
  - [If nutritional supplements are administered in the wrong indwelling state, there is a risk of causing serious complications such as peritonitis due to leakage into the abdominal cavity.]
- [3] There should be no pressure on the gastric mucosa or skin due to excessive pulling of the catheter.
  - [There is a risk of buried bumper syndrome.]

### [CONTRAINDICATIONS • PROHIBITION]

Do not reuse the product (single use only).

#### <Applicable target (patients)>

Do not apply in the following cases as a risk of adverse events.

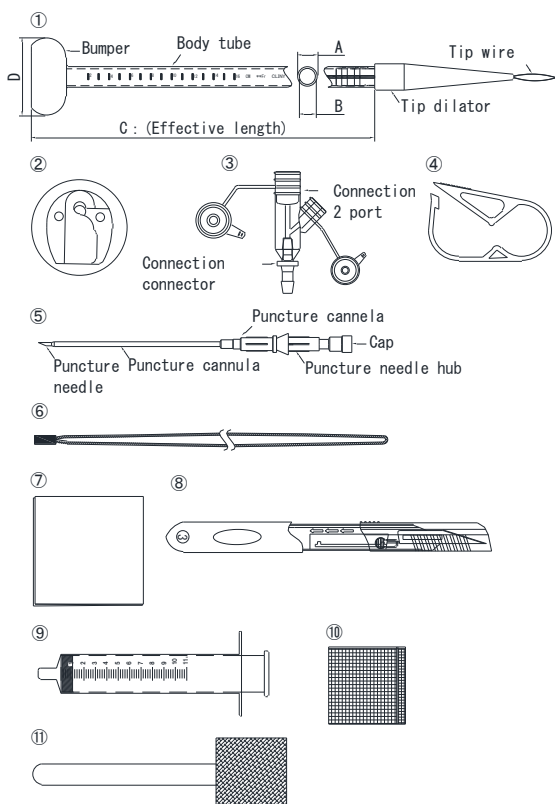
- [1] Patients whose stomach wall is not in contact with the abdominal wall.
- [2] Patients with granulation tissue, infection or inflammation around the fistula.
- [3] Patients with intense physical activity.

### [Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

- The connection 2 port adapter is used polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate).
- This product (tip wire, puncture needle, loop wire, small incision scalpel) is used metal.

#### <Shape>



No	Component	Quantity
①	PULL method PEG bumper catheter	1
②	Compact fixing plate	1
③	Connection 2 port adapter	1
④	Clamp	1
⑤	Introducer cannula with inner needle (14 G)	1
⑥	Loop wire (PULL type)	1
⑦	Drape	1
⑧	Small incision scalpel (No.11) safe type	1
⑨	Syringe 10 mL	1
⑩	Gauze	1
⑪	Disinfection sponge	1

#### ①PULL method PEG bumper catheter

Size	Tube O.D. (A)	Tube I.D. (B)	Effective length (C)	Bumper diameter (D)
16Fr	φ5.3mm	φ3.0mm	700mm	φ21.5mm
20Fr	φ6.7mm	φ4.2mm	700mm	φ25.0mm

#### <Raw Materials>

- ①PULL method PEG bumper catheter: Silicone, ABS, SUS
- ②Compact fixing plate: Silicone
- ③Connection 2 port adapter: PVC, PP
- ④Clump: PP
- ⑤Introducer cannula with inner needle (14 G): SUS, PP, FEP/BaSO<sub>4</sub>, PE
- ⑥Loop wire (PULL type): SUS(Nylon coating)
- ⑦Drape: Paper, PE
- ⑧Small incision scalpel (No.11) safe type: ABS, stainless
- ⑨Syringe 10mL: PP, butyl rubber
- ⑩Gauze: Cotton
- ⑪Disinfection sponge: ABS, PU

#### <Principles>

The PULL method PEG catheter which forms the gastrostomy is secured by a bumper in the stomach and a compact fixing plate on the abdominal wall.

#### [Intended purpose, efficacy or effect]

Used for nutritional administration by gastrostomy in cases such as oral tumors and pharyngeal tumors that require urgent nutritional administration.

#### [Operating or using method]

The below is a general procedure.

##### <Placement method>

- [1] The endoscope is inserted into the stomach according to the prescribed procedure.
- [2] The stomach is sufficiently inflated by insufflation, and the skin at the position where the transmitted light is strongest in the irradiated gastric curvature is pressed. The appropriate gastrostomy site is determined by endoscopically confirming the ridge of the gastric cavity.
- [3] A snare is inserted through the endoscopic channel and waits in the stomach.
- [4] Make a skin incision at the appropriate location using a small incision scalpel. (Make a skin incision of at least 1 cm.)
- [5] An introducer cannula with an internal needle is inserted through the skin incision site, after confirming the arrival in the stomach with an endoscope, the puncture needle is removed.
- [6] Insert the loop part of the loop wire from the puncture cannula into the stomach and pull out of the oral cavity together with the endoscope while firmly grasping the loop wire with the snare.
- [7] When the loop wire is pulled out sufficiently, remove the snare and connect the tip wire of the catheter to the loop wire.
- [8] After applying lubricant to the catheter, hold the loop wire coming out of the incision site, pull the catheter into the oral cavity by pulling slowly. After passing

through the esophagus and into the stomach, pull out of the body together with the puncture cannula from the incision site. At that time, do not pull it forcibly and pull out with putting your hand lightly.

- [9] When the catheter bumper touches the anterior wall of the stomach lightly, reinsert the endoscope and check that it is properly placed.
- [10] A compact fixing plate is passed through the tip of the catheter and fixed at the incision site.
- [11] Cut the catheter vertically, leaving a length suitable for nutrition. Attach the connection 2-port adapter to the cut end.

#### <Removal method>

Endoscopic removal method (recommended method)

- [1] Remove the compact fixing plate and slide it from the abdomen.
- [2] The endoscope is inserted into the stomach according to the prescribed procedure.
- [3] Check if the bumper can be held by insufflating air.
- [4] While checking if the catheter has adhered to the fistula, turn slowly and push into the stomach by about 1 to 2 cm.
- [5] Insert the snare and firmly hold the bumper.
- [6] After disconnecting the catheter near the skin on the body surface, the bumper held with the endoscope is pulled out of the oral cavity.

#### <Precautions for the using method>

- [1] Make sure to flush with lukewarm water before and after nutritional administration.  
[It is necessary to prevent catheter clogging due to accumulation of residues such as nutritional supplements.]
- [2] Note that administration of powdered medicine, etc. (especially drugs containing binders, etc. as additives) via the catheter may clog the catheter.
- [3] If it felt resistance when administering nutritional supplements or flushing with lukewarm water, etc., stop the operation.  
[If the catheter lumen may be obstructed and the operation is continued without clearing the obstruction of the catheter lumen, the internal pressure of the catheter may rise excessively and cause damage or rupture.]
- [4] Please note the following when performing the operation to clear the catheter blockage.
  - Use a syringe with a large capacity.  
[Injectors with volumes smaller than 10 mL have higher injection pressure and are more likely to break or rupture the catheter.]
  - Do not use stylets, etc.
  - If the catheter is still clogged after performing the procedure, remove the catheter.

#### [Precautions]

##### <Important basic caution>

- [1] Do not pinch the device with forceps too strongly.  
[The tube may be broken or lumen may be occluded.]
- [2] During use, regularly check for damage to this product, loose joints, leaks, etc.
- [3] Note that di (2-ethylhexyl) phthalate, which is a plasticizer for polyvinyl chloride, may elute in fat-soluble pharmaceuticals or chemicals.  
[Polychlorinated vinyl chloride is used for the connection 2 port adapter.]

#### <Failures \* Adverse events>

##### Failures

The following failures may be caused by the use of the product:

- [1] Bumper disconnection.  
[May cause ileus.]
- [2] Deformation and rupture of tube  
[Rupture by the following causes]
  - Damage caused by handling during insertion (damage caused by forceps, scissors, knife, other apparatuses)
  - Other complex causes caused by the above events.
- [3] Accidental or natural removal.  
[Accidental or natural removal by the following causes]
  - A patient with intense physical activity.
  - Other complex causes caused by the above events.
- [4] Leakage of nutrients from around the gastrostomy.
- [5] Catheter position movement or out of position.

[The catheter may be pulled into the intestine and cause ileus.]

#### Adverse events

The following adverse events may be caused by the use of the product:

- Peritonitis
- Accidental puncture into other organs
- Stomach bleeding
- Pyloric stenosis
- Small bowel obstruction
- Gastric ulcer
- Wound infection
- Granulation

#### [Storage conditions and duration of use]

##### <Storage conditions>

Store the product hygienically, avoiding the direct sun light, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

##### <Expiration date >

See the expiration date given on each package provided that the device is stored appropriately.

[By self-authentication (our data).]

##### <Expiration date >

This product has developed as "use within 90 days".

[By self-authentication (our data).]

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### Manufacturer

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