

Endoscopic Gastrostomy (PEG) KIT

Instructions for Use

Doc. No.: CE/TD-EGK-22-02

Ver.:A. 03

Date of Release:2025.07.28

[WARNING]

- Please read this instruction before use. Use strictly according to the specifications in the instruction.
- This product is sterilized with ethylene oxide, with a shelf life of 3 years.
- Do not use after expiration. The production date and expiration date are indicated on the product primary package.
- Carefully check the packaging for integrity before use; do not use if the primary packaging is damaged.
- This product is for single use only; reuse is strictly prohibited. Attempts to reprocess, re-sterilize, and/or reuse may result in product failure and/or transmission of disease.
- Any serious incidents related to this product should be reported to the competent authorities of the EU member state where the manufacturer, user and/or patient are located.

[PRODUCT NAME]

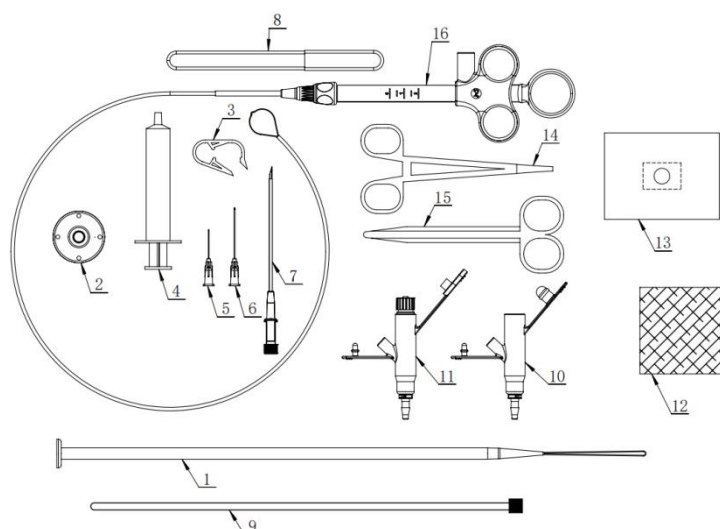
Endoscopic Gastrostomy (PEG) KIT

[INTENDED USE]

This product is suitable for long-term percutaneous gastric feeding, gastric decompression or gravity drainage.

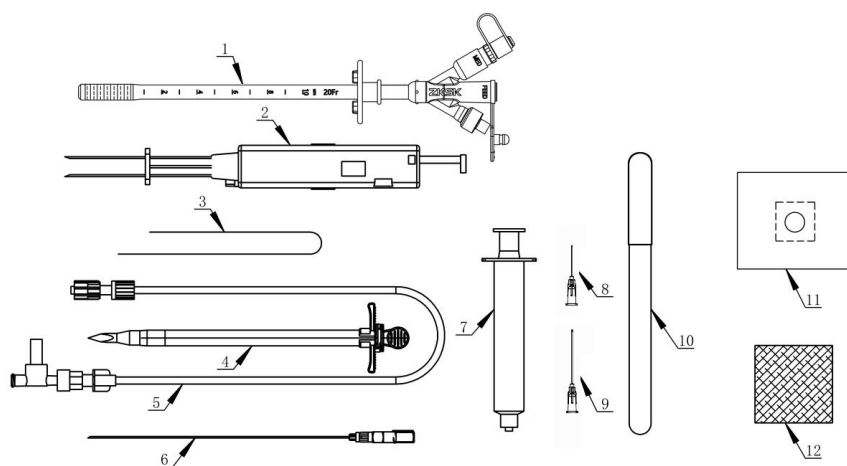
[PRODUCT COMPONENTS]

The Endoscopic Gastrostomy (PEG) KIT is classified into K-type, L-type, P-type, PL-type, T-type, and TL-type based on the specifications of the Gastrostomy tube and components. The basic structural components are shown in Figures 1, Figures 2 and Figures 3. The specifications and models of product, specifications and dimensions of each component and main materials are listed in Table 1. This product is for single use, sterilized with ethylene oxide, provided sterile, and has a shelf life of 3 years.



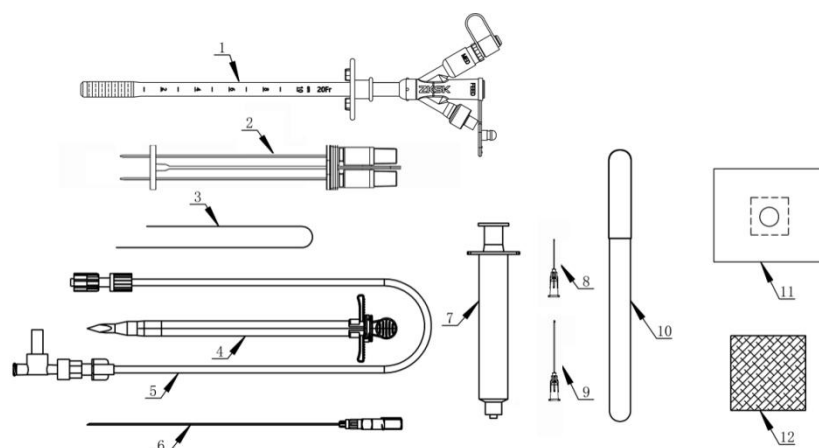
1. Gastrostomy tube 2. Fixed ring 3. Tubing clamp 4. Syringe 5. Injection needles(25g) 6. Injection needles(19g) 7. Puncture assembly 8. Disposable scalpel with #11 blade 9. Placement wire 10. Feeding Y joint 11. Feeding E joint 12. Gauze sponges 13. Hole towel 14. Hemostat 15. Surgical scissors 16. Retractor

Figure 1: Schematic composition diagram of K-type L-type Endoscopic Gastrostomy (PEG) KIT
(K-type does not include 14. Hemostat 15. Surgical scissors 16. Retractor)



1. Gastrostomy tube 2. II-type Gastric wall lavage fixator 3. Suture 4. Tearable puncture assembly 5. One-way injection needle 6. Extended introducer needle 7. Syringe 8. Injection needles(25g) 9. Injection needles(19g) 10. Disposable scalpel with #11 blade 11. Hole towel 12. Gauze sponges

Figure 2: Schematic composition diagram of P-type PL-type Endoscopic Gastrostomy (PEG) KIT
(P-type does not include 5. One-way injection needle 6. Extended introducer needle)



1. Gastrostomy tube 2. I-type wall Gastric lavage fixator 3. Suture 4. Tearable puncture assembly 5. One-way injection needle 6. Extended introducer needle 7. Syringe 8. Injection needles(25g) 9. Injection needles(19g) 10. Disposable scalpel with #11 blade 11. Hole towel 12. Gauze sponges

Figure 3: Schematic composition diagram of T-type TL-type Endoscopic Gastrostomy (PEG) KIT

(T-type does not include 5. One-way injection needle 6. Extended introducer needle)

[NAMING RULE]

GT □F - □

(1) (2) (3)

(1) Product name code

(2) Gastrostomy tube specification code

(3) Component code

Example: GT12F-K, 12F indicates the outer diameter of Gastrostomy tube is 12Fr (4.0mm), K refers to the components described in Table 1.

[SPECIFICATIONS AND MODELS]

Table 1: Specification and model of Endoscopic Gastrostomy (PEG) KIT

Model	Gastrostomy Tube			Balloon	Component
	French standard	Tube body outside diameter	Tube body length	Rated volume (ml)	
GT12F-K	12Fr	4.0	600	/	Gastrostomy tube, Fixed ring, Tubing clamp, Syringe, Injection needles (25G), Injection needles (19G), Puncture assembly, Disposable scalpel with #11 blade,
GT14F-K	14Fr	4.7		/	
GT16F-K	16Fr	5.3		/	
GT18F-K	18Fr	6.0		/	
GT20F-K	20Fr	6.7		/	

GT22F-K	22Fr	7.3		/	Placement wire, Feeding Y joint, Feeding E joint, Gauze sponges, Hole towel.
GT24F-K	24Fr	8.0		/	
GT12F-L	12Fr	4.0	600	/	Gastrostomy tube, Fixed ring, Tubing clamp, Syringe, Injection needles (25G), Injection needles (19G), Puncture assembly, Disposable scalpel with #11 blade, Placement wire, Feeding Y joint, Feeding E joint, Gauze sponges, Hole towel, Hemostat, Surgical scissors, Retractor.
GT14F-L	14Fr	4.7		/	
GT16F-L	16Fr	5.3		/	
GT18F-L	18Fr	6.0		/	
GT20F-L	20Fr	6.7		/	
GT22F-L	22Fr	7.3		/	
GT24F-L	24Fr	8.0		/	
GT12F-P	12Fr	4.0	185	5	Gastrostomy tube, II-type Gastric wall lavage fixator, Suture, Tearable puncture assembly, Syringe, Injection needles (25G) , Injection needles (19G), Disposable scalpel with #11 blade, Hole towel, Gauze sponges.
GT14F-P	14Fr	4.7		5	
GT16F-P	16Fr	5.3		20	
GT18F-P	18Fr	6.0		20	
GT20F-P	20Fr	6.7		20	
GT12F-PL	12Fr	4.0	185	5	Gastrostomy tube, II-type Gastric wall lavage fixator, Suture, Tearable puncture assembly, One-way injection needle, Extended introducer needle, Syringe, Injection needles(25G) , Injection needles (19G), Disposable scalpel with #11 blade, Hole towel, Gauze sponges.
GT14F-PL	14Fr	4.7		5	
GT16F-PL	16Fr	5.3		20	
GT18F-PL	18Fr	6.0		20	
GT20F-PL	20Fr	6.7		20	
GT12F-T	12Fr	4.0	185	5	Gastrostomy tube, I-type Gastric wall lavage fixator, Suture, Tearable puncture assembly, Syringe, Injection needles(25G) , Injection needles (19G), Disposable scalpel with #11 blade, Hole towel, Gauze sponges.
GT14F-T	14Fr	4.7		5	
GT16F-T	16Fr	5.3		20	
GT18F-T	18Fr	6.0		20	
GT20F-T	20Fr	6.7		20	
GT12F-TL	12Fr	4.0	185	5	Gastrostomy tube, I-type Gastric wall lavage fixator, Suture, Tearable puncture assembly,
GT14F-TL	14Fr	4.7		5	

GT16F-TL	16Fr	5.3		20	One-way injection needle, Extended introducer needle, Syringe, Injection needles(25G) , Injection needles (19G), Disposable scalpel with #11 blade, Hole towel, Gauze sponges.
GT18F-TL	18Fr	6.0		20	
GT20F-TL	20Fr	6.7		20	

[PRODUCT PERFORMANCE]

- 1.The flow rate of the Gastrostomy tube should not be less than 9 mL/min.
- 2.The connection between the Feeding joint and the Feeder or Enteral nutrition catheter should withstand a linear tensile force of 15N without breaking or separating.
- 3.For the Balloon with a rated volume of 5ml, the burst volume should be ≥ 10 ml; For a Balloon with a rated volume of 10ml, the burst volume should be ≥ 20 ml; For a Balloon with a rated volume of 20ml, the burst volume should be ≥ 40 ml.
- 4.The Luer fittings should comply with the specifications in ISO 80369 - 7: 2021.
- 5.This product is for single use, sterilized with ethylene oxide, provided sterile, and has a shelf life of 3 years.

[INDICATIONS]

Long-term intragastric feeding in patients with inadequate oral nutritional intake (< 60% of the calculated energy supply) and the need for nutritional feeding for a period exceeding 2-3 weeks,

Palliative gastric decompression/drainage by gravity

- in the presence of a chronic gastrointestinal stenosis or ileus
- severe stenosis of the oesophagus
- oesophageal varices
- oesophageal diverticula
- corrosive burns in the upper gastrointestinal tract
- tumors in the ENT area -tube placed before surgical procedure
- radiotherapy or surgery of the upper gastrointestinal tract
- previous operations on the mouth or pharynx
- only nasal endoscopy possible

[CONTRAINDICATIONS]

Contraindications include, but are not limited to:

- Lack of transillumination and positive needle aspiration test
- Interposed organs
- Serious coagulation disorders
- Marked peritoneal carcinomatosis
- Severe ascites

- Peritonitis
- Anorexia nervosa
- Serious psychosis
- Patients in terminal stage
- Severe erosive gastritis/ulcer
- Tumor infiltration at the puncture site
- Severe general wound-healing disorders
- Sepsis
- Acute pancreatitis
- Obstructions in the lower gastrointestinal tract
- Visible liver tumor
- Immune suppression
- Peritoneal dialysis (PD)
- Ventriculoperitoneal shunt

[POTENTIAL COMPLICATIONS]

Potential complications associated with the indwelling and use of the Endoscopic Gastrostomy (PEG) KIT include, but are not limited to:

- Skin breakdown
- Infection
- Hypergranulation tissue
- Gastric or duodenal ulcers
- Intraperitoneal leakage
- Pressure necrosis.
- Buried bumper

[CLINICAL BENEFITS]

Provide patients with effective enteral nutrition support to improve patients' nutritional status

[TARGET POPULATION]

Long-term intragastric feeding in patients with inadequate oral nutritional intake (< 60% of the calculated energy supply) and the need for nutritional feeding for a period exceeding 2-3 weeks; Patients who need palliative gastric decompression/drainage by gravity.

[INTENDED USERS]

The operators of this device must be physicians or medical personnel under the supervision of a physician, and they must have received adequate clinical technical training.

[PRECAUTIONS FOR USE]

1. Do not excessively pull on the Gastrostomy tube, as this can lead to complications such as necrosis of the fistula. Applying excessive pressure on the Balloon can cause the Balloon to rupture.

2. When administering powdered medications through the Gastrostomy tube (especially those containing binders as additives), be careful not to clog the Gastrostomy tube.
3. When administering nutrients or flushing the Gastrostomy tube with lukewarm water, if resistance is felt during the procedure, please stop the operation. There may be a blockage in the Gastrostomy tube. If injection is attempted while the tube is blocked, the internal pressure of the tube may increase, potentially leading to rupture or disconnection of the Gastrostomy tube.
4. When attempting to unblock a clogged Gastrostomy tube, it is recommended to use a large-capacity Syringe (30mL or above). Using a small Syringe may cause excessive injection pressure, which could lead to damage or even rupture of the Gastrostomy tube. Do not use a guide wire or metal placement wire for the unblocking procedure. If the blockage cannot be cleared, replace the Gastrostomy tube.
5. The Balloon of the indwelling Gastrostomy tube may rupture due to other reasons. It is important to regularly monitor and manage it.
6. Once a week, please withdraw all the sterilized distilled water from the Balloon and then inject the specified volume of new sterilized distilled water.
7. This product is not a Gastrostomy tube designed for long-term indwelling. Please regularly check the condition of the distilled water in the Balloon, and it is recommended to replace the Gastrostomy tube after continuous use for 30 days.
8. When inserting the Gastrostomy tube, the procedure must be performed under endoscope and X-ray guidance. Forcing the insertion may cause tissue damage. If insertion is difficult, stop the procedure and take appropriate action.
9. During indwelling, please pay attention to the management of the position of the Fixed ring.
10. During indwelling, pay attention to the patient's condition.
11. After indwelling, pay attention to monitoring the condition of this product. If any abnormalities occur, stop use and take appropriate action.
12. This product contains silicone. For patients allergic to silicone, stop use immediately and take appropriate measures.

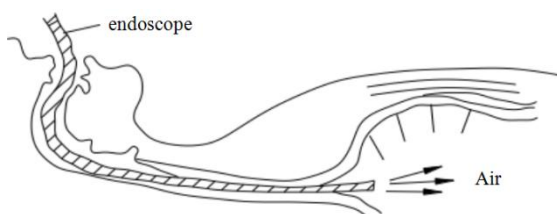
[IMPORTANT BASIC PRECAUTIONS]

- Do not modify this product, such as adding side holes, as it may cause the product to break.
- This product should not be exposed to strong acids, strong alkalis, or organic solvents.

- In case of packaging or product damage, please stop use.
- Use immediately after opening, and dispose of the product safely after use.
- When using this product to inject medication into the body, an appropriate medication should be selected under the supervision of a physician.
- During indwelling, untrained personnel should not operate the product. Proper management and attention are required.
- During indwelling, pay attention to monitoring the position of the Fixed ring. The Gastrostomy tube may be pulled into the stomach due to factors such as gastric peristalsis, especially when the fistula is located at the gastric antrum.
- When performing an MRI on a patient with an indwelling Gastrostomy tube, the irradiation intensity should be below 1.5 Tesla.
- As this product is a medical device, please be sure to follow the instructions in the user manual during use.

[PREOPERATIVE PREPARATION AND EXAMINATION]/[SYSTEM PREPARATION]

1. The patient should be positioned in the left lateral position. After the surgeon confirms that the patient has no gastric lesions, the patient should be placed in the supine position. Inflate the stomach with air to bring the stomach wall close to the abdominal wall.



2. Another surgeon will confirm the position of the stomach by palpating the left upper abdomen (near the midpoint between the left costal margin and the umbilicus) and observing the light from the endoscope through the abdominal wall. Gently pressing the abdominal wall in this area with a finger will cause the anterior wall of the stomach to bulge, visible through the endoscope. After identifying an easily accessible area (preferably the body of the stomach), mark this area on the skin. Then, mark the puncture site for the Gastric wall lavage fixator both anteriorly and posteriorly at this location. Disinfect the entire abdominal wall around this area.

3. Perform local anesthesia on the puncture site and the Gastric wall lavage fixator puncture site. Slowly insert the Syringe vertically. Once the tip reaches the stomach, negative pressure will cause a

reflux of bubbles, which can be confirmed. At the same time, the endoscope can confirm that the Syringe has successfully penetrated into the stomach.

[INSTRUCTIONS FOR USE]

<Endoscopic Gastrostomy (PEG) KIT K-type, L-type>

1. Select the gastrostomy insertion site. This site (typically located at the upper left corner of the stomach) should not have large blood vessels, internal organs, or scars.
2. Cover the selected insertion site with a Hole towel. After local anesthesia, make a 1 cm incision on the skin.
3. Insert the Puncture assembly through the incision and advance it to penetrate the abdominal wall and gastric wall. (See Figure 1)
4. Remove the needle, insert the Placement wire through the Puncture sheath, use the Retractor to grasp the Placement wire, and retract the Retractor through the endoscope channel.

(See Figure 2)

5. Remove the endoscope and Placement wire from the pharynx, pull out about 5 inches (13 cm) of the Placement wire through the mouth, and slowly advance the Placement wire into the Puncture sheath, ensuring the Puncture sheath is in the abdominal wall, while the tail end of the Placement wire remains outside.

(See Figure 3)

6. Connect the Placement wire to the wire sleeve of the Seeker with wire at the front end of the Gastrostomy tube.

(See Figure 4)

7. Lubricate the Gastrostomy tube with a water-soluble lubricant, and use the Placement wire to pull the Gastrostomy tube through the pharynx and esophagus into the stomach.

(See Figure 5)

8. Reinsert the endoscope through the esophagus to monitor the position of the Gastrostomy tube in the stomach. Remove the Puncture sheath from the incision, and gently pull the expanding end of the Gastrostomy tube through the abdominal wall. Slowly rotate the Gastrostomy tube, continuously pulling outward until the end bowl-shaped object contacts the stomach wall.

Note: After the Gastrostomy tube is pulled through the abdominal wall, the scale markings on the tube can help the doctor determine if the Gastrostomy tube is in the correct position.

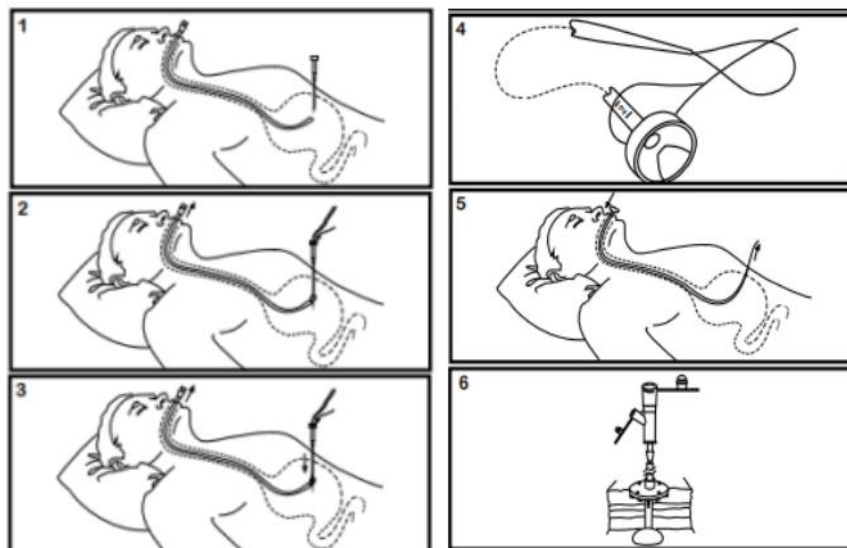
Note: Do not pull the Gastrostomy tube with excessive force, as this may harm the patient and damage the Gastrostomy tube.

9. Clean the Gastrostomy tube and the wound, apply a sterile hole gauze, and use scissors to cut off the wire sleeve end of the Gastrostomy tube, and Placement wire.

10. Insert the Fixed ring into the upper end of the Gastrostomy tube, push the Fixed ring to the position of the hole gauze, and confirm that the end bowl is in place. Remove the endoscope and tie a suture around the neck of the Fixed ring to prevent it from moving on the Gastrostomy tube.

11. Cut off the excess Gastrostomy tube, leaving an appropriate length, and attach the Feeding joint to the Gastrostomy tube.

Note: This joint needs to be compatible with the standard Feeding joint. (See Figure 6)

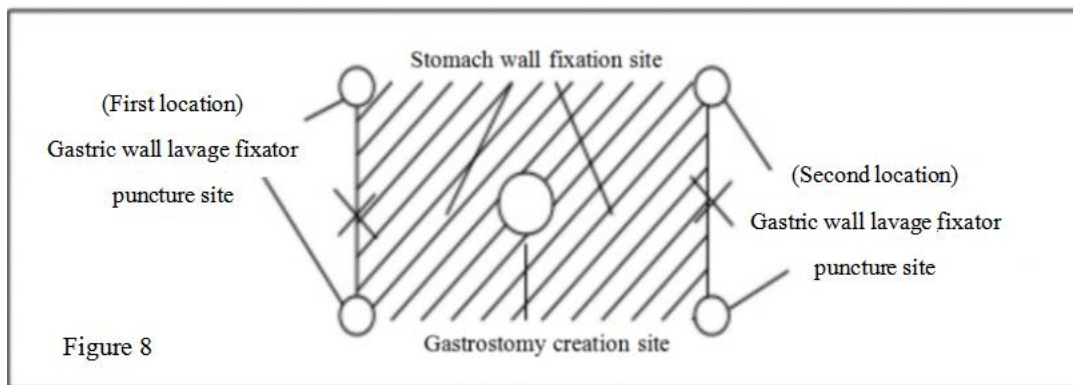
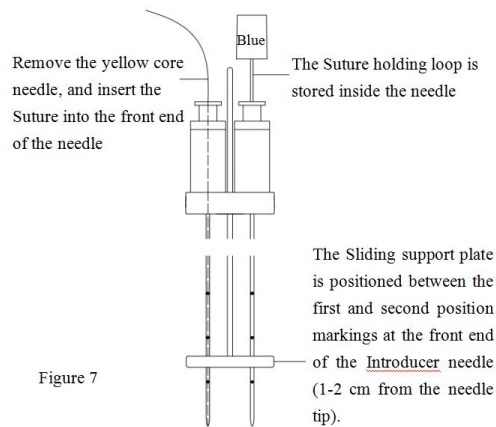


<Endoscopic Gastrostomy (PEG) KIT P-type, PL-type,T-type, TL-type>

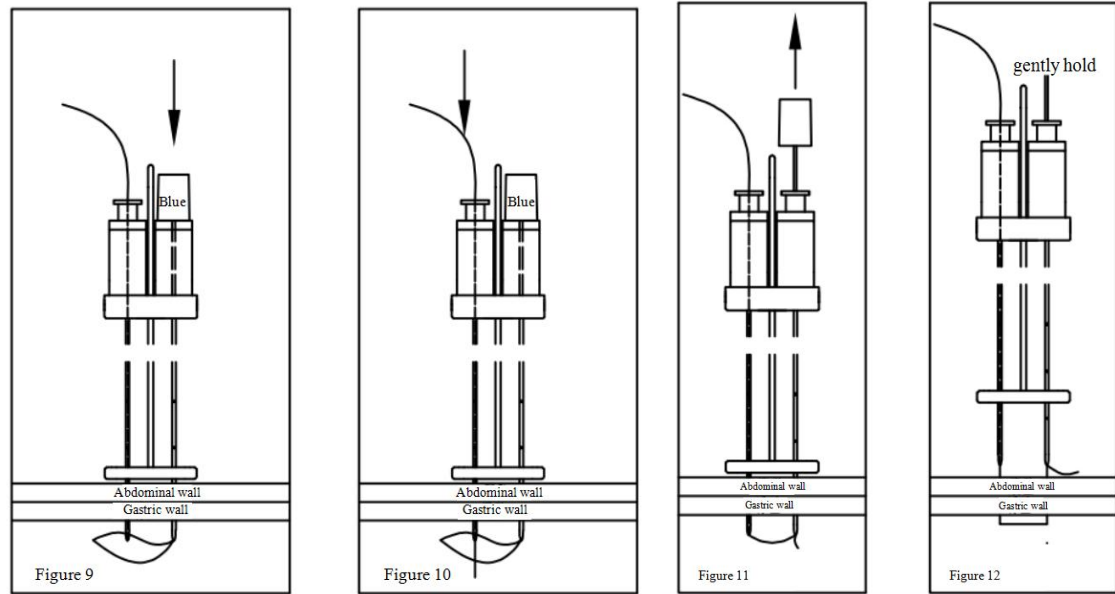
[Gastric wall lavage fixator]

I-type Gastric wall lavage fixator

1. Remove the yellow core needle from the wire insertion port, and insert the Suture into the front end of the needle. It is recommended to use a 2-0 suture. The Suture holding loop is stored inside the needle (set in the position shown in Figure 7). Then, insert both needles vertically into the marked puncture site of the Gastric wall lavage fixator (Figure 8).

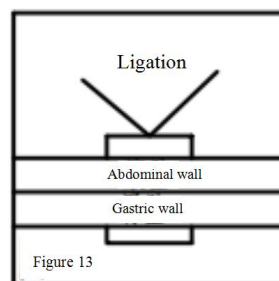


2. Under endoscopic guidance, once it is confirmed that both Introducer needles are accurately inserted into the stomach, insert the blue core needle with the marked protrusion facing inward. Push it in along this direction, and eventually, the protrusion at the handle of the core needle will align with the recessed part of the base. At this point, the Suture holding loop will form beneath the Introducer needle (Figure 9).
3. Insert the Suture through the Suture insertion port, continuing to pass the Suture through the suture holding loop (Figure 10).
4. After confirming under the endoscope that the Suture has passed through the Suture holding loop, raise the blue core needle until slight resistance is felt. This will cause the Suture to be retained inside the Introducer needle. The held Suture will form a held state at the front end of the Introducer needle (Figure 11).
5. When removing the I-type gastric wall lavage fixator, gently hold the blue core needle to prevent it from being pulled back. Induce each Suture through the puncture sites of the two Introducer needles to the outside of the body (Figure 12).



6. After completely inducing the Sutures to the outside, insert the blue core needle and release the Sutures. Tie the Sutures induced to the outside at the abdominal wall to Secure the gastric wall to the abdominal wall (Figure 13).

7. Continue assembling the I-type Gastric wall lavage fixator. Using the predetermined fistula site as the center, perform the gastric wall and abdominal wall ligation and fixation at the symmetric marked positions with the same method.



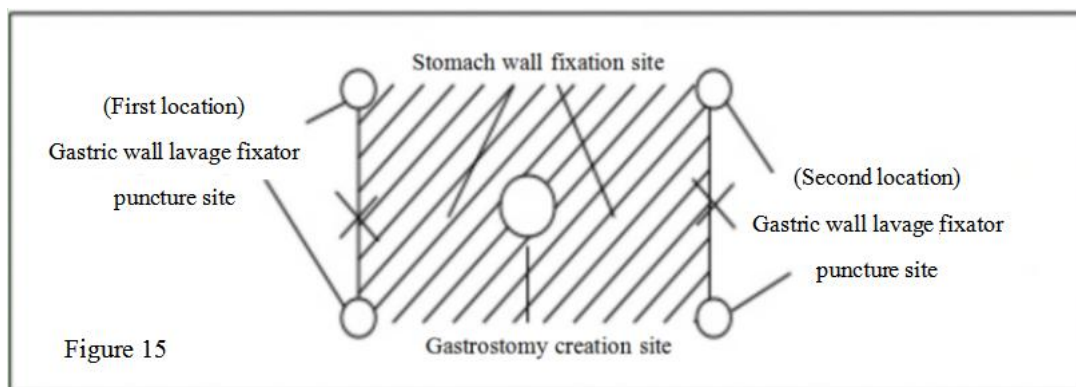
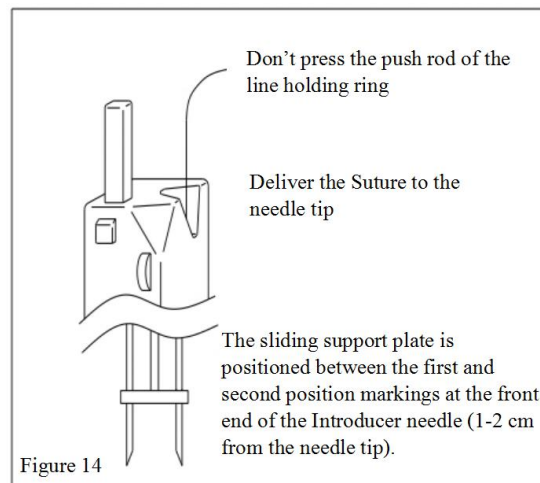
II-type Gastric wall lavage fixator

1. First, press the push rod of the line holding ring, and confirm whether the needle tip can form a line holding ring at the front end. Press the release button and confirm whether the line holding ring can retract. Check if the wire delivery roller can roll smoothly.

2. Assemble the II-type wall Gastric lavage fixator with the Suture (Suture compatible with this product). It is recommended to use a 2-0 Suture. Insert the Suture into the Suture insertion port and guide it to the wire delivery roller, then deliver it through the wire delivery roller to the needle tip (Figure 14). Confirm that the line holding ring is retracted inside the needle. If the line holding ring

is formed in front of the needle, press the release button to retract the line holding ring inside the needle.

3. Insert the two needles vertically into the marked puncture site of the Gastric wall lavage fixator (Figure 15).



4. Under endoscopy, confirm that both Introducer needles are accurately inserted into the stomach. Then, press the push rod of the line holding ring, and the line holding ring will form beneath the Introducer needle (Figure 16).

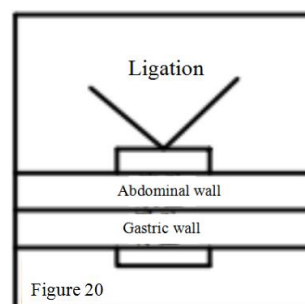
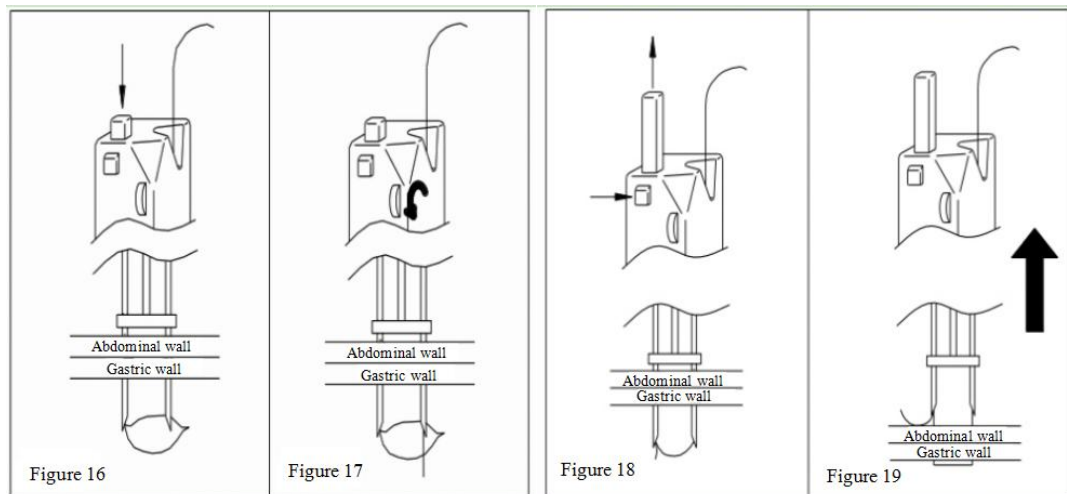
5. Gently rotate the wire delivery roller to deliver the Suture through the line holding ring (Figure 17).

6. After confirming under endoscopy that the Suture has passed through the line holding ring, press the release button to retract the line holding ring. The Suture held in place will form a holding state at the front end of the Introducer needle (Figure 18).

7. Gently remove the II-type Gastric wall lavage fixator, thereby guiding the Sutures from the puncture sites of the two Introducer needles to the exterior (Figure 19).

8. Once fully induced outside the body, press the push rod of the handle ring to release the Suture. Knot the Suture induced outside the body at the abdominal wall to fix the stomach wall to the abdominal wall (Figure 20).

9. Continue assembling the II-type Gastric wall lavage fixator. Using the predetermined fistula site as the center, perform the gastric wall and abdominal wall ligation and fixation at the symmetric marked positions with the same method.

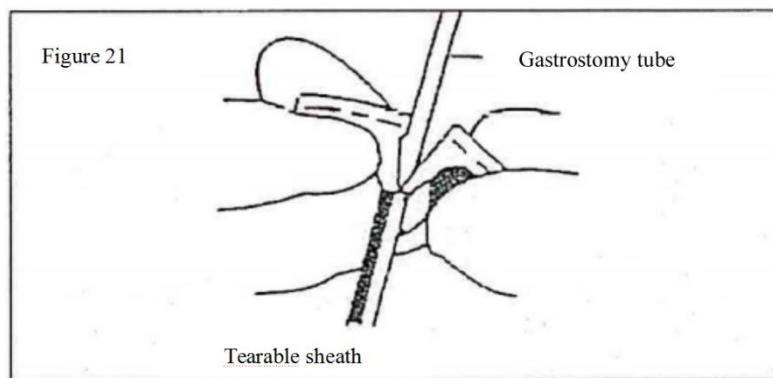


[Tearable puncture assembly]

1. At the predetermined fistula site on the abdominal wall, make a 10mm incision in the skin using a Disposable scalpel with #11 blade. Remove the Introducer needle protection cover and slowly insert the assembled Puncture assembly vertically.
2. Under endoscopy, if the tip of the Introducer needle has touched the anterior gastric wall, continue the puncture carefully and cautiously until the tip of the Introducer needle is observed to reach the stomach cavity.
3. Once the tip of the Introducer needle is visible inside the stomach, slowly advance the needle tip further.

4. Once the front end of the Puncture assembly has penetrated the anterior gastric wall and it is confirmed under endoscopy that the front end of the Tearable sheath has also reached the stomach, leave the Tearable sheath in place and remove the Introducer needle.

5. Immediately block the Tearable sheath with your finger to prevent air leakage, and insert the Gastrostomy tube until the entire scale on the tube body is fully inside.



[Indwelling Gastrostomy Tube]

1. Gently pull the Gastrostomy tube and use the endoscope to confirm whether the Balloon is tightly attached to the anterior gastric wall.

2. Move the Fixed ring assembled on the Gastrostomy tube towards the abdominal wall side, gently pull it to the abdominal wall, and fix it in place.

[Gastrostomy Tube Exchange Method]

1. Check whether the fistula has formed and if there are no abnormalities (three weeks after performing percutaneous endoscopic gastrostomy, which is typically during the fistula formation period, confirm whether there is any separation between the stomach wall and the abdominal wall).

2. Apply lubricant to the inner lumen of the end of the Gastrostomy tube left in the fistula, and insert the exchange Guide bar.

3. According to the method of removing the Gastrostomy tube left in the fistula, pull out the Gastrostomy tube without pulling out the exchange Guide bar at the same time.

4. Apply lubricant to the fistula site.

5. Along the exchange Guide bar, insert the Gastrostomy tube into the fistula hole from the front end, allowing the Balloon to reach the stomach.

6. Inject the specified amount of sterilized distilled water into the Balloon via the Filling joint of the Gastrostomy tube, expanding the Balloon.

7. Gently pull the Gastrostomy tube upwards and confirm that the Balloon inside the stomach is lightly in contact with the stomach wall, then remove the exchange Guide bar.

8. Move the Fixed ring towards the abdominal wall side. The appropriate position is when it does not contact the skin (with 1-2 cm excess at the body surface).

9. Use an endoscope to confirm the condition of the Gastrostomy tube inside the stomach.

[Measures in Case of Accidental Gastrostomy Tube Removal or Gastrostomy Tube Displacement]

1. Check for any abnormality in the fistula hole and apply lubricant to the fistula and exchange Guide bar.

2. Insert the exchange Guide bar into the fistula hole.

3. Follow the steps 5-9 of the [Gastrostomy Tube Exchange Method] above to confirm the proper placement and insertion of the Gastrostomy tube inside the stomach.

- The fistula hole will contract and narrow in a short period without any Gastrostomy tube in place. To prevent the fistula hole from narrowing, the Gastrostomy tube exchange should be performed promptly.
- Forced insertion may damage the fistula hole. If the fistula hole is already narrowed, stop the procedure and take other appropriate measures.

[Method for Removing the Gastrostomy Tube]

1. Use a Syringe to withdraw the sterilized distilled water from the Balloon.

2. Slowly pull out the Gastrostomy tube from the fistula hole.

[Management of the Gastrostomy Tube After Percutaneous Endoscopic Gastrostomy (PEG)]

1. For the first 3 weeks after performing the percutaneous endoscopic gastrostomy, during the fistula formation period, frequent management of the Gastrostomy tube is required.

Postoperative confirmation matters:

- Confirm whether the Balloon contains any liquid other than sterilized distilled water.
- Gently pull to confirm that the Balloon is in an expanded state.
- Confirm that the Fixed ring is not sutured to the skin.
- Carefully pull the Gastrostomy tube without applying excessive force.
- Be cautious of the risk of unconscious pulling or self-removal of the Gastrostomy tube by the patient. Using an abdominal binder or other means of concealment is one way to prevent this.

2. Confirmation matters on the day after surgery:

- Inject 500 ml of 10% glucose solution into the Gastrostomy tube's Feeding joint and check the patient's condition. If no abnormalities are found, nutritional solutions can begin to be administered through the Gastrostomy tube the following day.

3. Emergency measures:

- Within 3 weeks after percutaneous endoscopic gastrostomy (before fistula formation), if the Gastrostomy tube is accidentally displaced, keep the patient still and attempt to insert a Gastrostomy tube of the same size.

[Precautions Related to Usage Method]

1. After inserting the Gastrostomy tube, confirm with an endoscope that the front end of the Gastrostomy tube is in the correct position.
2. After the wire holding ring expands inside the stomach, avoid letting the ring contact the stomach's inner or posterior wall. Otherwise, the ring may deform, invert, or cause incorrect puncturing of the stomach wall.
3. The Introducer needle of the Puncture assembly must be used under endoscopic guidance. Be careful to avoid puncturing the posterior stomach wall.
4. Before use, confirm the Balloon is able to expand and contract by injecting air into the Balloon.
5. Be cautious when injecting sterilized distilled water into the Balloon. Rapid injection, although causing minimal pressure, may lead to the detachment of the Filling joint.
6. Do not exceed the specified amount of sterilized distilled water in the Balloon, as over-inflation may increase the load of Balloon and cause rupture.
7. When connecting the feeding bag to the Gastrostomy tube's end, ensure that the connectors are properly compatible. After use begins, confirm that the connection is leak-free and securely attached.

[Adverse Events and Handling Measures]

① Balloon Rupture

[The following causes may lead to Balloon rupture]

- Damage caused by instruments during insertion (damage caused by clamps, forceps, scissors, scalpels, and other instruments).
- Over-injection (injecting more than the product's specified volume).

- Accidental injection of other substances during Balloon expansion (such as saline, contrast agents, or substances with components that can easily coagulate).
- Sudden load caused by self-removal of the product.
- Other causes due to the above factors.

Handling Measure: If the Gastrostomy tube balloon ruptures, replace the Gastrostomy tube following the Gastrostomy tube exchange method.

② Gastrostomy Tube Occlusion

[The lumen of the Gastrostomy tube may become blocked due to the adhesion of nutritional solutions.]

Handling Measure: Use warm water to clean the lumen of the Gastrostomy tube. If the blockage is severe and cannot be cleared, replace the Gastrostomy tube with a new one.

③ Gastrostomy Tube Cannot Be Removed

[If the lumen of the Gastrostomy tube is not cleaned properly, causing adhesion of nutritional solutions or other materials, the Gastrostomy tube may deform, and the Balloon cavity may become blocked, unable to pump. If saline or contrast agents are used to expand the Balloon, their components may coagulate, causing unable to pump water to keep the balloon from contractin.]

Handling Measure: Cut the part of the Gastrostomy tube outside the body, and use an endoscope to remove the portion of the Gastrostomy tube inside the body. Then, replace the Gastrostomy tube with a new one.

④ Gastrostomy Tube Fracture

- Damage caused by instruments during insertion (damage caused by clamps, forceps, scissors, scalpels, and other instruments).
- Sudden load caused by self-removal or other causes.
- Other compound causes due to the above factors.

Handling Measure: Use an endoscope to remove the fractured Gastrostomy tube and replace it with a new one.

⑤ Fixed Ring Loosening

[Forced pulling of the Gastrostomy tube may cause deformation of the Gastrostomy tube, leading to loosening of the Fixed ring.]

Handling Measure: Replace the Gastrostomy tube following the Gastrostomy tube exchange method.

⑥ Filling Joint Damage and Leakage

[Localized high-frequency heating may cause damage to the valve, leading to leakage.]

Handling Measure: If a valve is damaged and the Balloon cannot be inflated, replace the Gastrostomy tube with a new one.

⑦ Deformation of Gastric Wall Lavage Fixator's Wire Holding Ring and Inability to Open

[Improper operation of instruments such as clamps or forceps may cause deformation of the wire holding ring, making it impossible to open.]

Handling Measure: If deformation or failure to open the wire holding ring of the Gastric wall lavage fixator is observed, stop using it and replace it with a new Gastric wall lavage fixator for the procedure.

[Complications and Handling Measures]

After percutaneous endoscopic gastrostomy (PEG), the following complications may occur:

- ◆ Ulceration caused by contact between the front end of the Gastrostomy tube and the stomach wall

Handling Measure: Immediately stop using the Gastrostomy tube, remove it with an endoscope, and appropriately treat the ulcer.

- ◆ Gastrostomy tube displacement due to damage at the tube end or other incidents (such as self-removal), leading to failure of stoma formation and wound infection.

Handling Measure: First, check for any abnormality in the fistula hole and replace the Gastrostomy tube following the Gastrostomy tube exchange method.

- ◆ Expansion of the fistula hole during Gastrostomy tube replacement

Handling Measure: Immediately stop the procedure and replace the Gastrostomy tube with one that is appropriately sized for the fistula hole.

- ◆ Gastrointestinal obstruction and complications from obstruction (such as difficulty in gastric fluid drainage, gastric distension, vomiting, etc.).

Handling Measure: Identify the cause of the gastrointestinal obstruction and provide appropriate treatment based on the patient's symptoms.

[WASTE DISPOSAL]

Disposable Pulse Lavage should be disposed of by the using healthcare organisation in accordance with the disposal procedures for disposable medical consumables.

[DATE OF MANUFACTURE]

See the label on product primary package.

[STERILIZATION METHOD]

Ethylene oxide sterilization.

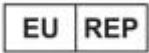
[EXPIRATION DATE]

3 years

[STORAGE AND TRANSPORTATION CONDITIONS]

The product should be protected from heavy pressure, direct sunlight, and rain during transportation. It should be stored indoors in a clean, well-ventilated environment, avoiding sunlight and corrosive gases.

[SYMBOLS DESCRIPTION]

	Manufacturer		Authorized representative in the European Community
	Catalogue number		Lot number
	Date of manufacture		Expiration date
	Do not re-use		Do not use if primary package is damaged
	Consult instructions for use		Caution
	Sterilized using ethylene oxide, single sterile barrier system with protective packaging outside		Unique device identifier
	Keep away from sunlight		Keep away from rain
	European Conformity		Medical device

	Package quantity		Stacking limit by number
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[CONTACT INFORMATION]

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