CLINY

# All Silicone Ileus Tube
# GW Set

Do not reuse

**[CONTRAINDICATIONS, PROHIBITIONS]**

[1] Do not reuse the product (single use for one case).
[The product is single use only and disposable, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of the product may lead to patient injury, illness or death.]

[2] Prohibition of reprocessing, re-sterilization.
[Reprocessing of the product may lead to defects. It may also cause patient injury, illness or death.]

**< Target patients >**

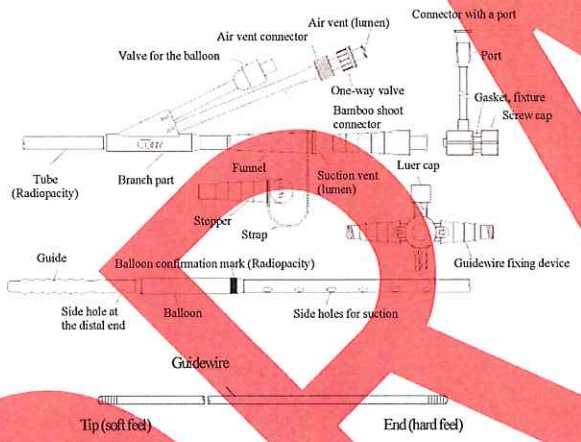
Do not use the product for patients with esophageal stenosis, pyloric stenosis, strangulated ileus, ileus due to impaired blood flow associated with mesenteric thrombosis, ileus paralytic, volvulus, incarcerated hernia, or intussusception.
[Because Ileus tube is not indicated or emergency operation is required due to impaired blood circulation.]

**[SHAPE, STRUCTURE AND PRINCIPLE]**

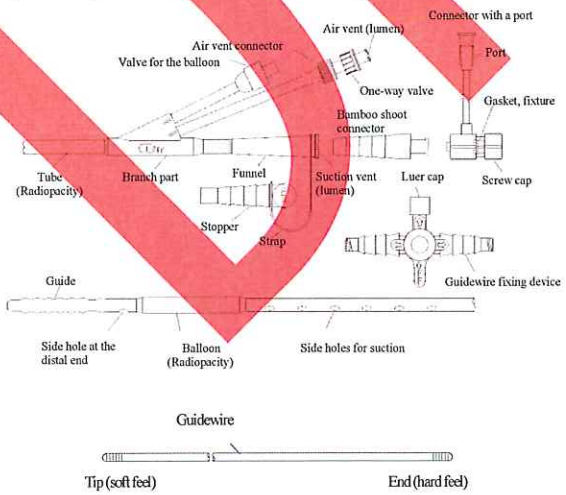
- The product is sterilized with ethylene oxide gas.
- Polyvinyl chloride (plasticizer: di- (2-ethylhexyl) phthalate) is used in the product (connector with a port, strap).
- Metals are used in the product (Guide, Guidewire).

**< Shape >**

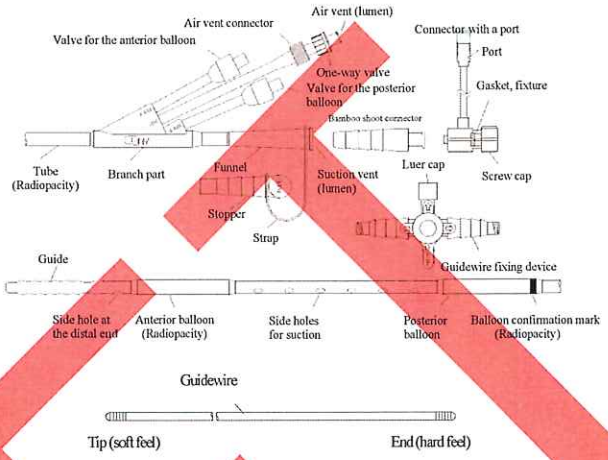
- Ileus Tube (Single Balloon Type)
(12Fr•14Fr•20Fr)




- Ileus Tube (Single Balloon Type)
(16Fr•18Fr)




- Ileus Tube (Double Balloon Type)




* Bamboo shoot connector, Connector with a port, Stopper, Strap, Guidewire fixing device, Guidewire may not be included.

* Description of accessories

- One-way valve
Prevent leakage of intestinal contents, etc. from the air vent. It is attached to the air vent and can be detached.
- Stopper
Used as a stopper of the suction vent to prevent the discharge of intestinal contents, etc. from the vent. The stopper is connected to the funnel with a strap.
- Connector with a port, bamboo shoot connector
Used to inject olive oil or MCT oil into the lumen of the tube with the guidewire is being inserted, to maintain the slipperiness of the guidewire. When injecting the olive oil or MCT oil, screw the screw cap.
- Guidewire
Used as a guidewire for Open Tip Type and as a stylet for Closed Tip Type.
- Guidewire fixing device
When fixing the guidewire to the tube, the fixation of the guidewire is improved by passing the guidewire through the lumen of the fixture and pinching it with the lever.

- Ileus Tube (Single Balloon, Open Tip Type)

| Size | Total length of catheter | Balloon capacity | Guidewire*2 | Placement method*1 |
|---|---|---|---|---|
| 16Fr | 2400mm | 30mL | C | b |
| | | | E | b or c |
| 18Fr | 2400mm | 30mL | C | b |
| | | | E | b or c |

- Ileus Tube (Single Balloon, Closed Tip Type)

| Size | Total length of catheter | Balloon capacity | Guidewire*2 | Placement method*1 |
|---|---|---|---|---|
| 12Fr | 1800mm | 15mL | A | a |
| 14Fr | 2400mm | 30mL | B | a |
| 16Fr | 2400mm | 30mL | C | a |
| | 3000mm | 30mL | D | a |
| 18Fr | 2400mm | 30mL | C | a |
| 20Fr | 2400mm | 30mL | C | a |

- Ileus Tube (Double Balloon, Open Tip Type)

| Size | Total length of catheter | Balloon capacity | Guidewire *2 | Placement method*1 |
|---|---|---|---|---|
| 16Fr | 3000mm | 60mL | D | b |
| | | | E | b or c |
| 18Fr | 3000mm | 60mL | D | b |
| | | | E | b or c |

- Ileus Tube (Double Balloon, Closed Tip Type)

| Size | Total length of catheter | Balloon capacity | Guidewire *2 | Placement method*1 |
|---|---|---|---|---|
| 16Fr | 3000mm | 60mL | D | a |
| 18Fr | 3000mm | 60mL | D | a |

*1 For the placement method, see the section of **[OPERATING AND USING METHOD]**.

*2 For the guidewire standard, see the table below.

- Depth mark

| Size | Mark position |
|---|---|
| L-3000 | At 10cm intervals between 50cm and 260cm from the tip |
| L-2400 | At 50, 60, ..., 140, 150 and 200cm from the tip |
| L-1800 | At 10cm intervals between 50cm and 150cm from the tip |

- Guidewire

| | Guidewire name | Outer diameter | Total length | Specification |
|---|---|---|---|---|
| A | G/W.043"2300T | 1.09mm (0.043") | 2300mm | Fixed straight (Soft tip) Teflon-coated |
| B | G/W.043"3000T | | 3000mm | |
| C | G/W.052"3000T | 1.32mm (0.052") | 3000mm | |
| D | G/W.052"3500T | | 3500mm | |
| E | G/W.052"4500T | | 4500mm | |

### < Raw materials >

- Ileus tube: Silicone rubber, Stainless steel, Polyester or Polycarbonate, Polypropylene
- Bamboo shoot connector: Acrylic resin
- Connector with a port: Polyvinyl chloride, Silicone rubber, Polyacetal, Nylon ABS alloy
- Guidewire : Stainless steel, Polytetrafluoroethylene
- Guidewire fixing device: Polycarbonate, Polyacetal, Polypropylene

### < Principle >

The product is nasally inserted into the stomach and intestine, and the balloon is inflated for placement. Decompression and suction of intestinal contents (liquid/gas) and injection of a contrast medium are performed.

### [INTENDED USE]

It is used as a long tube for ileus inserted nasally.

### [EFFICACY OR EFFECT]

- It can be nasally inserted into the stomach and intestine, fixed and placed.
- Decompression and suction of intestinal contents (liquid/gas) and injection of a contrast medium can be performed.

### [PERFORMANCE]

- Secure the sterility assurance level (SAL) $10^{-6}$.
- Sterile residues: Shall conform to ISO10993-7.
- Shall not contain biological substance and conform to biological safety requirements.
- Shall be durable for 29 days continuous use.
- Shall maintain the stability and durability for 5 years.
- Tensile strength
  When both ends of the ileus tube are stretched in the length direction with a load of 20N, they shall not be broken.
  When both ends of the guidewire are stretched in the length direction with a load of 2.45N, they shall not be broken.

### [OPERATING AND USING METHOD]

The general operational procedure is described below.

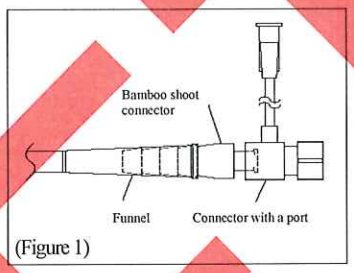
### < Items to be prepared >

- Lubricant or surface anesthetic
  Used for nasopharyngeal surface anesthesia. Smooth insertion of the tube and superficial anesthesia of the naso-pharyngeal region can reduce the patient's pain during insertion.
- Olive oil or MCT oil
  Used to smoothly manipulate the guidewire.
- Syringe (25 – 50mL)
  Used for balloon inflation, injection from the connector with a port, and injection of contrast medium.
- Sterile distilled water
  Used to smoothly inflate the balloon.
- Contrast medium
  Used for radiological enteroclysis immediately after insertion of the tube. In case of obstruction of the proximal small intestine, the obstruction site can be identified by radiological enteroclysis. It is preferable to use a water-soluble contrast medium for the gastrointestinal tract.

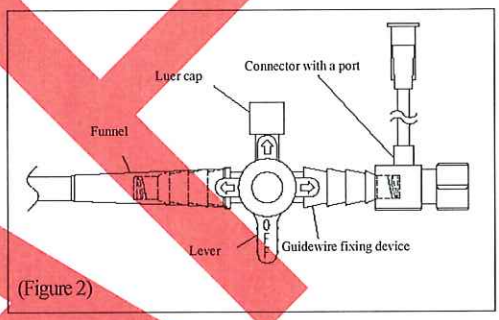
### < Placement method a (using the Closed Tip Type) >

[1] Before inserting the tube, aspirate the gastric content (air, gastric juice, etc.) sufficiently. If the gastric content is sufficiently aspirated with a stomach tube and so on, it is possible to prevent the balloon in the duodenum from returning to the stomach by vomiting movement.

[2] Fully fill the tube with olive oil or MCT oil from its suction vent to tip side hole and attach the connector with a port to the suction vent.
Attachment methods of the connector with port are as follows:
- Attach the bamboo shoot connector to the suction vent, and then attach the connector with a port. (Figure 1)
- Attach the guidewire fixing device to the suction vent and then the connector with a port. (Figure 2)



(Figure 1)



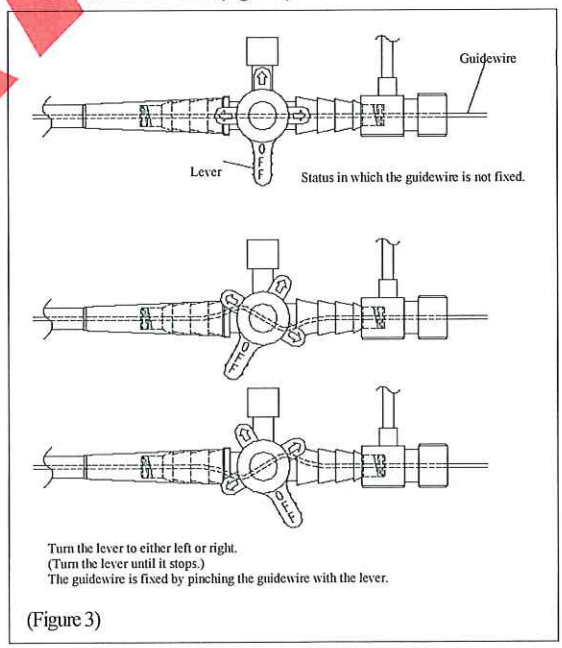
(Figure 2)

[3] Apply an appropriate amount of lubricant or surface anesthetic to the tube tip.

[4] After slowly inserting the tube nasally into the stomach, insert the guidewire from the screw cap of the connector with a port to the tip of the suction lumen.

[5] During the procedure, tighten the screw cap on the connector with a port, and inject olive oil or MCT oil not less than 20mL from the port if necessary.

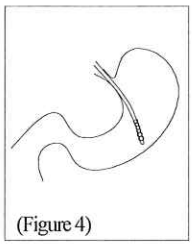
[6] Insert the tube while fixing the guidewire as needed.
To fix the guidewire, turn the lever of the guidewire fixing device to pinch the wire in the fixture lever. (Figure 3)

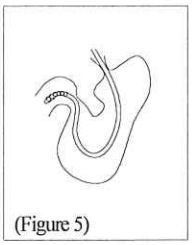


(Figure 3)

[7] Under X-ray fluoroscopic guidance, in the semi-upright and left anterior oblique position, direct the tip of the tube to the antrum of the stomach. (Figure 4)

[8] With the tip of the tube facing the pylorus in the right lateral position, push the guidewire in place of the stylet to advance the tube, and confirm that the tip of the tube passes through the pylorus. (Figure 5)
[9] When the tip of the tube passes through the pylorus, pull out the guidewire by about 5cm from the tube, and repeat the procedure of intubation (insertion) of the tube by about 5cm, and push the tube forward as much as possible.
[10] After determining the placement position, inject 10 – 15mL (15mL or less for 12Fr, and 30mL or less for 14Fr, 16Fr, 18Fr, and 20Fr) of sterile distilled water into the balloon. (Figure 6)
[11] Remove the guidewire.
[12] After removing the guidewire, insert the tube into the stomach and keep it loose. Make sure that the side holes of the tube have fully entered the intestinal tract.
[13] While the balloon is transported to the occlusion site by peristaltic movement, perform suction and decompression.
[14] When it reaches the target position, inject the contrast medium from the suction vent.


(Figure 4)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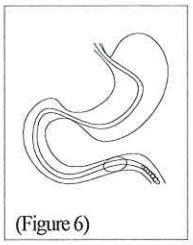
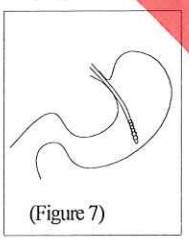
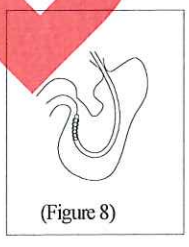

(Figure 6)

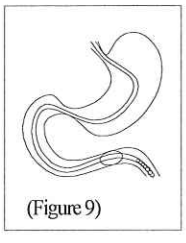
**< Placement method b (using the Open Tip Type, but without endoscope) >**

[1] Before inserting the tube, aspirate the gastric contents (air, gastric juice, etc.) sufficiently. If the gastric contents is sufficiently aspirated with a stomach tube and so on, it is possible to prevent the balloon in the duodenum from returning to the stomach by vomiting movement.
[2] Fully fill the tube with olive oil or MCT oil from its suction vent to tip side hole and attach the connector with a port to the suction vent.
Attachment methods of the connector with port are as follows:
- Attach the bamboo shoot connector to the suction vent, and then attach the connector with a port. (Figure 1)
- Attach the guidewire fixing device to the suction vent and then the connector with a port. (Figure 2)

[3] Apply an appropriate amount of lubricant or surface anesthetic to the tube tip.
[4] After slowly inserting the tube nasally into the stomach, insert the guidewire from the screw cap of the connector with a port to the tip of the suction lumen.
[5] During the procedure, tighten the screw cap on the connector with a port, and inject olive oil or MCT oil not less than 20mL from the port if necessary.
[6] Insert the tube while fixing the guidewire as needed.
To fix the guidewire, turn the lever of the guidewire fixing device to pinch the wire in the fixture lever. (Figure 3)
[7] Under X-ray fluoroscopic guidance, in the semi-upright and left anterior oblique position, direct the tip of the tube to the antrum of the stomach. (Figure 7)
[8] With the tip of the tube facing the pylorus in the right lateral position, advance the guidewire from the guide in this state, and confirm that the guidewire passes through the pylorus. (Figure 8) If the guidewire does not pass through the pylorus at this point, insert an endoscope orally and guide the guidewire to the pylorus using forceps, etc.
[9] When the tip of the tube passes through the pylorus, pull out the guidewire by about 5cm from the tube, and repeat the procedure of intubation (insertion) of the tube by about 5 cm, and push the tube forward as much as possible.
[10] After determining the placement position, inject 10 - 15mL (30mL or less) of sterile distilled water into the balloon. (Figure 9)
[11] Remove the guidewire.
[12] After removing the guidewire, insert the tube into the stomach and keep it loose. Make sure that the side hole of the tube has fully entered the intestinal tract.
[13] While the balloon is transported to the occlusion site by peristaltic movement, perform suction and decompression.
[14] When it reaches the target position, inject the contrast medium from the suction vent.


(Figure 7)


(Figure 8)


(Figure 9)

**< Placement method c (using the Open Tip Type and endoscope) >**

[1] Before inserting the tube, aspirate the gastric content (air, gastric juice, etc.) sufficiently. If the gastric content is sufficiently aspirated with a stomach tube and so on, it is possible to prevent the balloon in the duodenum from returning to the stomach by vomiting movement.
[2] Insert an endoscope orally to the descending limb of the duodenum.
[3] Insert a guidewire from the forceps opening and place it in the descending limb of the duodenum under X-ray fluoroscopic guidance.
[4] Remove the endoscope slowly while paying attention not to pull out the guidewire at the same time.
[5] Insert an appropriate tube (that can insert a guidewire into the lumen) from the nasal cavity and pull it out to the oral cavity.
[6] Insert the rear end of the guidewire into the lumen of the tube pulled out to the mouth and ligate it. After pulling the guidewire into the nasal cavity, remove the tube.
[7] Fully fill the tube with olive oil or MCT oil from its suction vent to tip side hole and attach the connector with a port to the suction vent.
The connector with a port can be attached in the following manner.
- Attach the bamboo shoot connector to the suction vent, and then attach the connector with a port. (Figure 1)
- Attach the guidewire fixing device to the suction vent and then the connector with a port. (Figure 2)

[8] Apply an appropriate amount of lubricant or surface anesthetic to the tube tip.
[9] Insert the tube nasally and slowly along the guidewire to reach the descending limb of the duodenum.
[10] During the procedure, tighten the screw cap on the connector with a port, and inject olive oil or MCT oil not less than 20 mL from the port if necessary.
[11] Insert the tube while fixing the guidewire as needed.
To fix the guidewire, turn the lever of the guidewire fixing device to pinch the wire in the fixture lever. (Figure 3)
[12] Inject 10 - 15mL (30 mL or less) of sterile distilled water into the balloon.
[13] Remove the guidewire.
[14] After removing the guidewire, insert the tube into the stomach and keep it loose. Make sure that the side hole of the tube has fully entered the intestinal tract.
[15] While the balloon is transported to the occlusion site by peristaltic movement, perform suction and decompression.
[16] When it reaches the target position, inject the contrast medium from the suction vent.

**< Management method during tube placement >**

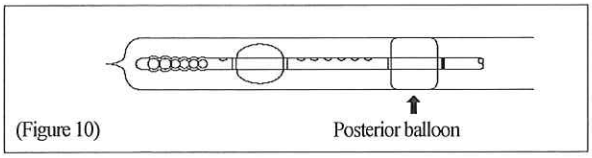
[1] While the balloon is transported to the occlusion site by peristaltic movement, perform intermittent or low-pressure continuous suction manually or with an aspirator to check the patency of the tube lumen as needed.
[2] Check the position of the tube appropriately with X-ray, etc.
[3] When the tube reaches the occlusion site, perform contrast imaging.

**< Tube removal method >**

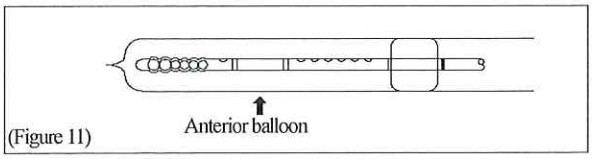
[1] Remove the sterile distilled water in the balloon with a syringe and deflate it completely.
[2] Gently remove the tube.

**< Using method of the posterior balloon (when using Double Balloon Type) >**

The use of a posterior balloon enables selective small bowel imaging.
[1] Use this method when the tube progression stops.
[2] Inflate the posterior balloon with 30 - 40mL (less than or equal to the maximum volume) of air and secure the tube in the intestinal tract before deflating the anterior balloon. This prevents backflow of contrast medium and return of the tube. (Figure 10)
[3] Remove the sterile distilled water in the anterior balloon to deflate it. (Figure 11)
[4] Inject a contrast medium from the suction vent. Prevent the contrast medium from flowing into the air vent by attaching a cap, etc. to the vent.
[5] Inject air from the air vent to perform double contrast imaging.



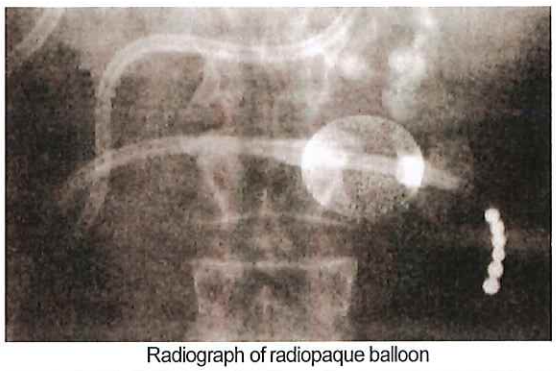
(Figure 10)



(Figure 11)

**< Using method of the radiopaque balloon (when using Contrast Balloon Type) >**

The radiopaque balloon is made using silicone rubber containing a contrast medium. During the processes of balloon inflation and deflation, or tube progress, the state of balloon inflation can be checked using X-ray; making procedures safer. (There is no balloon confirmation mark on the radiopaque balloon.)



Radiograph of radiopaque balloon

**< Medical devices to be used in combination >**

[1] When using the product, use it in combination with the following devices.

| Name | Specification |
|---|---|
| Syringe<br>Application:<br>Valve for the balloon<br>Connector with a port | - Slip type |
| Syringe<br>Application: Suction vent | Catheter tip type<br>- Volume: 25 ~ 50mL |
| MCT oil | - |
| Sterile distilled water | - |
| Low-pressure suction device | - Connecting tube of suction device<br>Catheter tip shape or bamboo shoot shape<br>- Suction pressure<br>-980 to -2450Pa (-10 to -25cmH2O) |
| Drainage bag | - |
| Lukewarm water | - |

[2] Drugs that can be used concomitantly with this product.

| Product name | Generic name |
|---|---|
| Gastrografin | Amidotrizoic acid |
| Olive oil | Olive oil |
| Xylocaine jelly | Lidocaine |

Do not use the drugs other than the above concomitantly.

**< Precautions in use related with the method of use >**

[1] Please note the following when inflating and deflating the balloons.

1) For the balloon inflation or deflation, use a general slip-type disposable syringe.
[Luer lock-type syringe cannot be inserted into the end of the valve firmly. And using a syringe with unfitted taper may cause breakage of the valve.]
2) Insert the tip of the syringe firmly to the end of the valve to inflate or deflate the balloon.
[If insertion of the tip of the syringe into the valve is insufficient, the valve may not operate properly to inflate or deflate the balloon.]
3) When removing the syringe, make sure to press the valve and rotate the syringe to remove.
[In rare cases, the valve may be dislocated or come off.]
4) Use sterile distilled water for single balloon and anterior balloon inflation and air for posterior balloon, and inject slowly and carefully.
[The valve may slip off rarely or it may come off in some cases due to the pressure when injected rapidly.]
5) Do not inject more than the maximum volume of sterile distilled water into the single balloon and the anterior balloon, and more than the maximum volume of air into the posterior balloon.
[Excessive injection leads to explosion of the balloons due to loads to them. In addition, the intestinal tract may be compressed firmly by the excessive pressure in the balloon due to excessive injection and damaged.]

[2] When inserting the guidewire, check the position of the tip under X-ray fluoroscopy.

[3] When inserting the guidewire, pay attention not to make the tip of the guidewire protruded from the side hole of the tube.
[If it is inserted with the tip protruding from the tube, the gastric wall and intestinal wall may be damaged or perforated.]

[4] When inserting the tube using the guidewire as stylet, prevent the guidewire from being protruded out of the aspiration side hole by twisting the tube and placing the suction inlet on the inside of bended tube. (To prevent damage of the intestinal tract, suction side holes are provided exclusively on one side of the tube.)
[If the guidewire protrudes from the side holes, the intestinal tract may be damaged.]

[5] Do not overtighten the screw cap of the connector with a port.
[It may cause inability of injecting olive oil or MCT oil.]

[6] Do not inject the contrast medium or drug solution that may crystallize into the connector with a port.
[It may cause clogging.]

[7] When using the Open Tip Type and the guidewire precedes the guide, take care not to perforate or damage the duodenum with the guidewire.

[8] When it is confirmed under X-ray fluoroscopy that the tube forms a loop in the stomach, remove the tube until the loop disappears and insert it again so that no loop is formed.
[If the tube forms a loop in the stomach, the force is not transmitted to the tube tip, making it extremely difficult to insert the tube and pass it through the pylorus.]

[9] When the tube passes through the pylorus, make sure that the guidewire can be removed from the tube.
[Note that if the tube is inserted too far into the duodenum, the guidewire may not be removed.]

[10] When fixing the guidewire onto the tube using guidewire fixing device, do not insert and remove the guidewire with the tube fixed on it.
[The guidewire may be damaged.]

[11] Remove the guidewire fixing device from the suction vent during the tube placement.

[12] If the guidewire cannot be removed from the tube, pull the tube tip back around the pylorus and then remove the guidewire.
[If the guidewire is removed forcibly, the tube may crack.]

[13] Before removing the guidewire, make the tube as straight as possible.
[If the tube is loose inside or outside the body, it may be difficult to remove the guidewire.]

[14] When performing suction, intermittent suction or low-pressure continuous suction, pay careful attention not to suction intestinal mucosa.
Intermittent suction: Should be performed with an aspirator or manually.
Low-pressure continuous suction: Appropriate suction pressure is -980 to -2450 Pa (-10 to -25cm$H_2O$).
[Intussusception may occur.]

[15] Do not fix the tube near the nose as it is transported by peristaltic movement. However, if it is considered necessary to fix the tube near the nose because of possible self-removal or reverse peristaltic movement due to nausea, keep the tube loose in the stomach.

[16] Do not inject the contrast medium or drug solution that may crystallize into the air vent.
[It may cause clogging and decrease the decompression and suction efficiency.]

[17] When connecting a low-pressure continuous aspirator, etc. to the suction vent, select the one that fits surely. During use, check the connection for leakage or loosening as appropriate, and keep it securely connected.

[18] When connecting the guidewire fixing device or bamboo shoot connector, etc. to the suction vent, insert the guidewire fixing device or bamboo shoot connector, etc. straight along the lumen of the suction vent. Do not apply a load such as bending, twisting, or pinching the funnel under this condition.
[The tip of the guidewire fixing device or bamboo shoot connector, etc. may damage the inner space of the funnel, leading to a crack or rupture of the funnel.]

[19] When using an endoscope be sure to refer to the package insert, etc. of each product.

**[PRECAUTIONS IN USE]**

**< Important basic precautions >**

[1] Be careful exercised as fat-soluble drugs or drug solutions, etc. may cause the elution of di- (2-ethylhexyl) phthalate, plasticizer of polyvinyl chloride.
[Polyvinyl chloride is used in the connector with a port and strap of the product.]

[2] Be careful as contact with oily ingredients such as castor oil, surfactants, or alcohol may crack the guidewire fixing device.

[3] Radiopaque balloon may discolor entirely or partially, but it doesn't affect the quality of balloon.

[4] During the placement, check the condition in the lumen and make sure that it is possible to perform decompression, aspiration, and injection properly. If a clogging occurs in the lumen, wash the tube lumen with lukewarm water.
[The lumen and side holes of the tube may be clogged by intestinal contents, contrast medium, etc.]

[5] During placement, the status of the tube and balloon should be periodically managed.

[Gastrointestinal perforation and laceration may be caused by the guide. Also, the balloon may deflate due to spontaneous leakage.]

[6] Do not block the air vent intentionally during decompression therapy.
[It may cause inability of decompression and aspiration.]

[7] Before using the product, check whether there is any abnormality in each part.

[8] Do not insert forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Tissues may be damaged.]

[9] Do not insert and remove the product forcibly. Operate the product with adequate care.
[The product may be damaged.]

[10] If any abnormality is observed, discontinue the use of the product immediately and take appropriate measures.

[11] Do not pull or bend the product forcibly during use. Handle it carefully.

[12] Do not modify the product.
[If a side hole, etc. is added, the tube may be cut.]

[13] Do not grip the product strongly with forceps, etc.
[Tube cut, lumen occlusion and balloon breakage may occur.]

[14] During use, check the connecting part for leakage or loosening appropriately, and keep it securely connected.

[15] MRI (Magnetic Resonance Imaging) should not be performed during the use of the product.
[Due to the influence of the high frequency electromagnetic field of MRI, metal parts may cause local high frequency heating and cause burns to the patient.]

[16] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.

[17] Use immediately after opening and dispose in a safe manner for each country after use.

[18] If drug solution is injected into the patient's body by using the product, select the appropriate drug solution under the responsibility of the physician.

[19] During placement, keep the product under full control to prevent its handling by an untrained person.

[20] 

printed on the label means that the product contains DEHP.

[21] When using the product in neonates or infants, and also in pregnant or lactating women, the risks associated with DEHP should be fully explained and their consent should be obtained. It can harm the liver and kidneys.

[22] 

printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.

[23]  printed on the label means that the product should not be used if the package is damaged or opened.

[24] Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

### < Defects/Adverse events >

#### Defects

[1] Balloon burst.
[Burst due to the following causes.]
- Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
- Excessive injection volume (injection of more than the capacity).
- Injection of the wrong substance for balloon inflation (substance that is likely to cause coagulation of components such as physiological saline and contrast medium).
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[2] Obstruction of the tube.
[The lumen of the tube may be occluded by intestinal contents, contrast medium, etc.]

[3] Impossibility of tube removal.
[If physiological saline or contrast medium is used to inflate the fixing balloon, the lumen of the fixing balloon may be obstructed in association with coagulation of the ingredients. Consequently, the drainage of water may become impossible.]

[4] Cut of the tube.
[Cut due to the following causes.]
- Damage caused by handling during insertion (Damage caused by tweezers, forceps, scissors, scalpel, or other instruments).
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[5] The metal ball of the guide is exposed or detached.
[If the guide is damaged, the metal ball may be exposed or detached.]

[6] Breaking, bending, damage, cutting of the guidewire.
- Forcible insertion, removal, excessive torque operation, etc.
- Use for kinked tubes.
- Excessive pinched by the fixture lever when securing the tube with the guidewire fixing device.
- Other multiple causes due to the above-mentioned events.

[7] Inability of removal of guide wires
(Inability of removal due to the following)
- Bending, bending, damage, cutting of the guide wire.
- Decrease in lubricity.
- Use for kinked tubes.
- Other multiple causes due to the above-mentioned events

#### Adverse events

[1] The following adverse events and contraindications are generally assumed by the use of the product.
Intraperitoneal infection due to hemorrhage, intestinal perforation, perforation, injury of nasal cavity/pharynx/esophagus, aspiration pneumonia, intestinal necrosis, ulcer due to intestinal compression, intussusception, nasal ala ulcer/necrosis, and residual in the body associated with tube breakage.

[2] The use of guide wires may cause the following adverse events.
- Damage (perforation, etc.)
- Bleeding

### < Use during pregnancy, delivery or lactation and pediatric use >

Be careful when using X-ray to the patient who is pregnant or has some possibility of pregnancy.
[The influence of X-ray to the fetus is concerned.]

### [STORAGE METHOD AND DURATION OF USE]

#### < Storage method >

Store the product cleanly. Avoid wetting, direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamp, etc.

#### < Expiration date >

The product has been developed as "Use within 29 days."
[Based on self-certification (our company data).]

#### < Duration of use >

When the proper storage method has been maintained, refer to the expiration date on the individual package.
[Based on self-certification (our company data).]

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