FRESENIUS KABI

# Freka® PEG Pro (Percutaneous Endoscopic Gastrostomy)

## long term enteral nutrition

**Product Codes:**
M90800346 (12 FR)
M90800347 (14 FR)
M90800349 (16 FR)
M90800348 (20 FR)

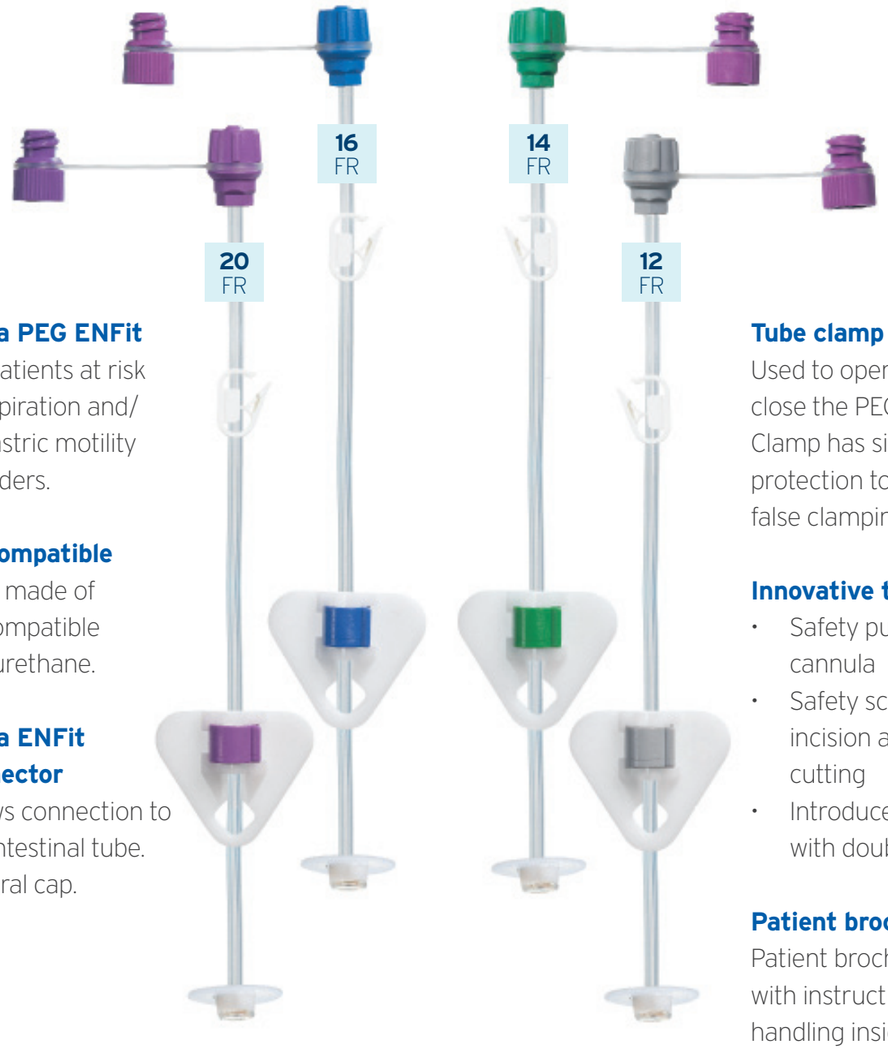

### Product features, surgical and insertion techniques for healthcare professionals

Insertion of PEG through endoscopic pull method.
Insertion of feeding tube into Freka PEG endoscopically.
Removal of feeding tube from Freka PEG.
Removal of Freka PEG endoscopically.

**12-14-16-20**
FR

freka.com.au

# Product features




**Freka PEG ENFit**
For patients at risk of aspiration and/or gastric motility disorders.

**Biocompatible**
Tube made of biocompatible polyurethane.

**Freka ENFit connector**
Allows connection to the intestinal tube. Integral cap.

**Tube clamp**
Used to open and close the PEG tube. Clamp has side wall protection to minimise false clamping.

**Innovative tools**
- Safety puncture cannula
- Safety scalpel for incision and thread cutting
- Introducer cone with double thread

**Patient brochure**
Patient brochure with instructions for handling inside box.

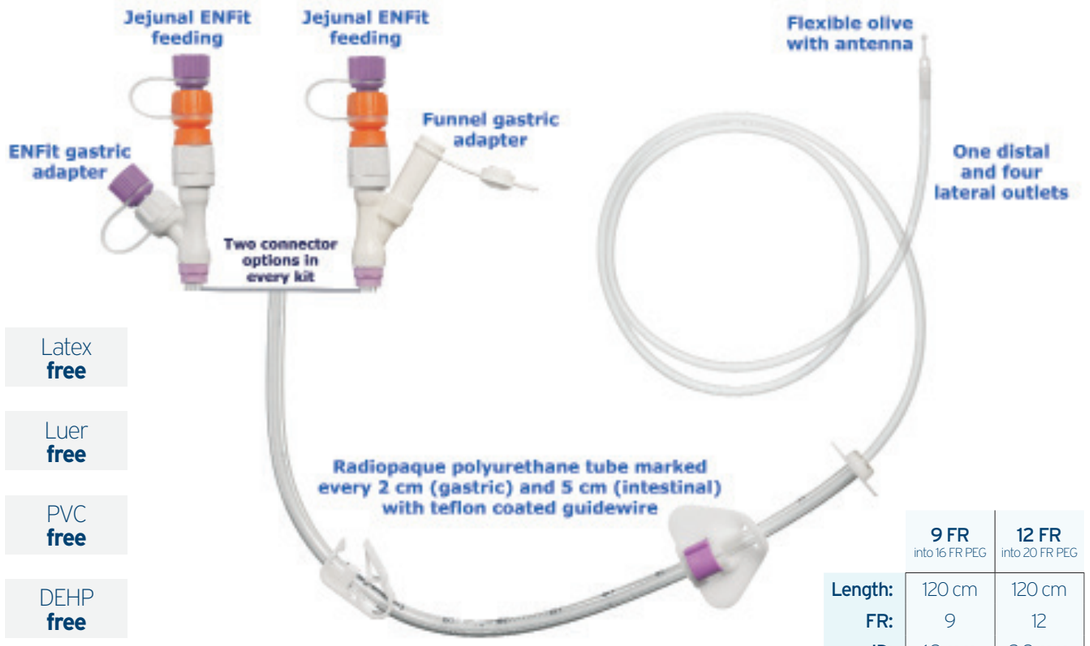
**12 FR:** Smallest tube for paediatric use with option of Freka Belly Button as replacement.
**14 FR:** Small adult feeding tube with option of Freka Belly Button/GastroTube as replacement.
**16 FR:** Standard feeding tube with Freka Belly Button/GastroTube as replacement.
**20 FR:** Large feeding tube for gastric decompression/medication administration with Freka Belly Button as replacement.

| | | Colour | Connector | External ø | Internal ø | Length | Sales unit |
|---|---|---|---|---|---|---|---|
| M90800346 | Freka PEG Pro Set 12 FR | grey | ENFit | 4.00 | 2.90 | 35 cm | 5 |
| M90800347 | Freka PEG Pro Set 14 FR | dark-green | ENFit | 4.66 | 3.45 | 35 cm | 5 |
| M90800349 | Freka PEG Pro Set 16 FR | dark-blue | ENFit | 5.33 | 4.05 | 35 cm | 5 |
| M90800348 | Freka PEG Pro Set 20 FR | purple | ENFit | 6.60 | 5.00 | 35 cm | 5 |



# Supporting products

## Freka double lumen intestinal/gastric tubes for Freka PEG Pro 16 FR and PEG Pro 20 FR




Latex **free**

Luer **free**

PVC **free**

DEHP **free**

| | 9 FR into 16 FR PEG | 12 FR into 20 FR PEG |
|---|---|---|
| **Length:** | 120 cm | 120 cm |
| **FR:** | 9 | 12 |
| **ID:** | 1.9 mm | 2.8 mm |
| **OD:** | 2.9 mm | 4.0 mm |

## Adapters and connectors

**Freka Click Adaptor, ENFit**
Adaptor for fixing Freka Intestinal Tube to Freka PEG Pro and the corresponding Y-connector. Available in sizes 9 FR and 12 FR, with colour-coding.

**Freka Y-connector**
Connector for connection of a gastric Freka PEG Pro with a Freka Intestinal Tube. Available in sizes 16/9 and 20/12 FR in ENFit/ENFit or ENFit/funnel options, with colour-coding.

## Repair kits

For repair of an in situ Freka PEG Pro. Kits available for 12 - 14 - 16 - 20* FR PEG repairs and contain: **Freka ENFit connector, fastening screw, tube clamp and fixation plate. *Note, 20 FR repair kit also includes replacement ENFit funnel adapter.**

# Safety first.  For all involved.

**The Freka PEG Pro is designed to help meet the needs of you and your patients in enteral tube feeding.** Learn about some of the innovative Freka PEG Pro safety and insertion features.


### PenBlade: Safety scalpel

Automatic retraction. Allows precise thread cutting through safety slot.

### ENFit connector

- Dedicated to enteral application.
- Avoids misconnections.

### Safety puncture cannula

- Puncture cannula with protective cap increases safety after puncture and during waste disposal.
- Air valve in puncture cannula reduces air escaping from the stomach during endoscopy.


### Gastropexy option

Gastropexy allows attachment of the gastric wall to the abdominal wall with sutures using a unique device available from Fresenius Kabi.

### Combines the benefits of two procedures

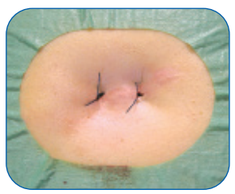
The technique combines the advantages of a conventional PEG placement using the pull method with the benefits of a secure adaptation of gastric wall and abdominal wall, independent of PEG fixation.

### Reduces complications significantly

Based on retrospective studies, direct puncture with gastropexy lowers PEG complications by up to 90% [1,2], safeguarding the stoma and preventing peritoneal gastric juice infiltration, thus reducing infection risks.

### Enhanced stoma healing

Unlike traditional PEG, after gastropexy, the outer PEG plate can be loosely fixed against the abdominal wall[1]. Thus, a better blood circulation around the stoma enhances stoma healing and early tube mobilisation prevents buried bumper syndrome[1,3,4].



1 Kishta J., Reich V., Bojarski C. Hybrid-PEG – Experiences after more than 300 hybrid PEGs at the Charité. Endo-Praxis 2021; 37: 95–99.

2 Leonie Schumacher, Christian Bojarski et. al, Complication rates of direct puncture and pull-through techniques for percutaneous endoscopic gastrostomy -Results from a large multicenter cohort, DOI: 10.1055/a-1924-3525, 08/2022

3 Devia J, Santivañez JJ, Rodríguez M, Rojas S, Cadena M, Vergara A. Early Recognition and Diagnosis of Buried Bumper Syndrome: A Report of Three Cases. Surg J (N Y). 2019 Aug 22;5(3):e76-e81. doi: 10.1055/s-0039-1692148. PMID: 31448333; PMCID: PMC6706275.

4. Cyrany J., Rejchrt S., Kapacova M., Bures J.  Buried bumper syndrome: A complication of percutaneous  endoscopic gastrostomy.  World Journal of Gastroenterology.  2016 Jan 14;22(2): 618-627.



# Clinical excellence

### Short term complications

In a randomised trial[1] the short term complications associated with polyurethane vs silicone PEG catheters was studied.

| | Freka Polyurethane PEG | Bard silicone PEG | Risk Ratio | Confidence interval |
|---|---|---|---|---|
| Placement difficulty | 6/51 | 2/57 | 0.30 | 95%, 0.06-1.43 |
| Short term complications | 3/51 | 17/57 | 4.35 | 95%, 1.36-14 |

**Use of a silicone PEG feeding tube was associated with a higher 28 day complication rate compared to a polyurethane PEG catheter.  This finding is of particular relevance when PEG feeding is used short term e.g. perioperatively.**

### Longevity

In another study[2], looking at the longevity of Freka PEG's placed in 277 patients with a median age of 74 years (IQR 59-82) PEG longevity was:

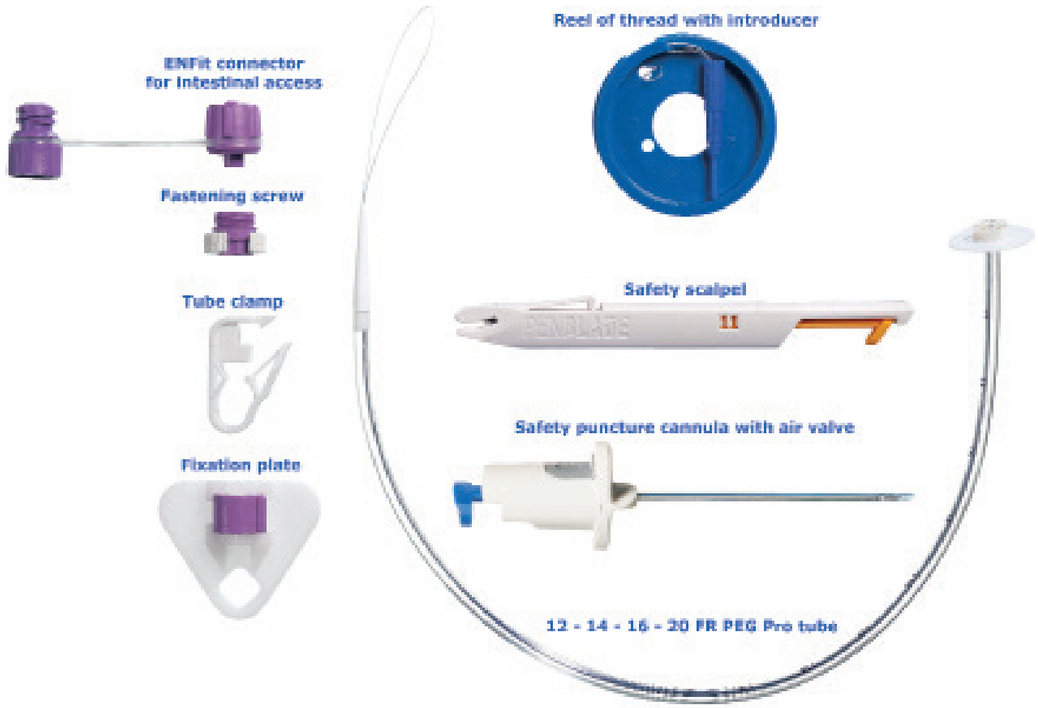

**In summary, the Fresenius Kabi Freka polyurethane PEG:**

- **has lower short term complications than the silicone BARD PEG[1]**
- **is a suitable long term option for patients (68.5% survivability at five years)[2].**

1. S.J. van den Hazel, G. dan Hartog, J.E. Thies and C.J.J Mulder. PEG feeding tubes: polyurethane (Freka PEG) versus silicone (BARD PEG).  A randomised trial.  Department of Gastroenterology, Rijnstate Hospital, Arnhem, The Netherland.  Abstracts of the Netherlands Gastroenterology and Hepatology Societies, A27. 1998.

2. Keith Siau, Tom Troth, Elizabeth Gibson, Anita Dhanda, Lauren Robinson, Neil C Fisher. How long do percutaneous endoscopic gastrostomy feeding tubes last? A retrospective analysis. Postgrad Med J, 2018;94:469-474.

## **Kit contents:** Freka PEG Pro ENFit




### Freka 12 - 14 - 16 - 20 FR PEG tube

35 cm polyurethane PEG tube with proximal cone and fixation loop.

### Safety puncture cannula

10 cm cannula used to penetrate the abdominal wall with safety air valve and tip retraction.

### Reel of thread

Used to assist in the pull method of placement. Double thread at end with introducer tool.

### Safety scalpel

PenBlade safety scalpel. Automatic retraction allowing precise thread cutting through safety slot.

### Freka ENFit connector with fastening screw

Allows connection to the PEG tube. Integral cap. ENFit. *Note, 20 FR also comes with ENFit funnel adapter included in the kit.

### Fixation plate and tube clamp with side walls

External fixation plate. Made of silicone rubber for patient comfort. Used to open and close the PEG tube. Clamp has side wall protection to minimise false clamping.

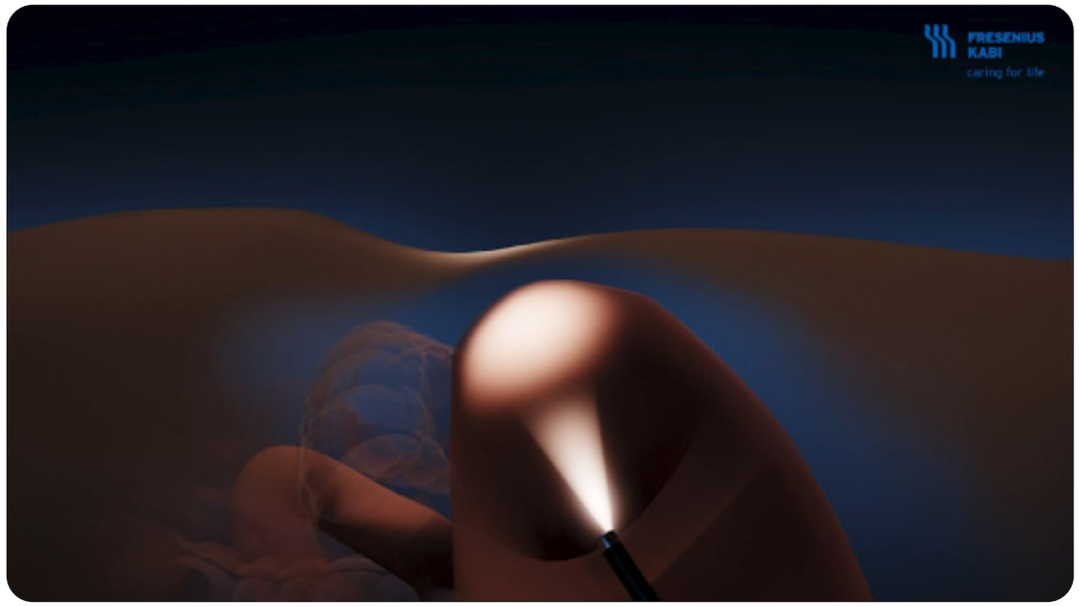
### Patient support

Each kit includes a patient support brochure, stickers with batch number and patient ID card.

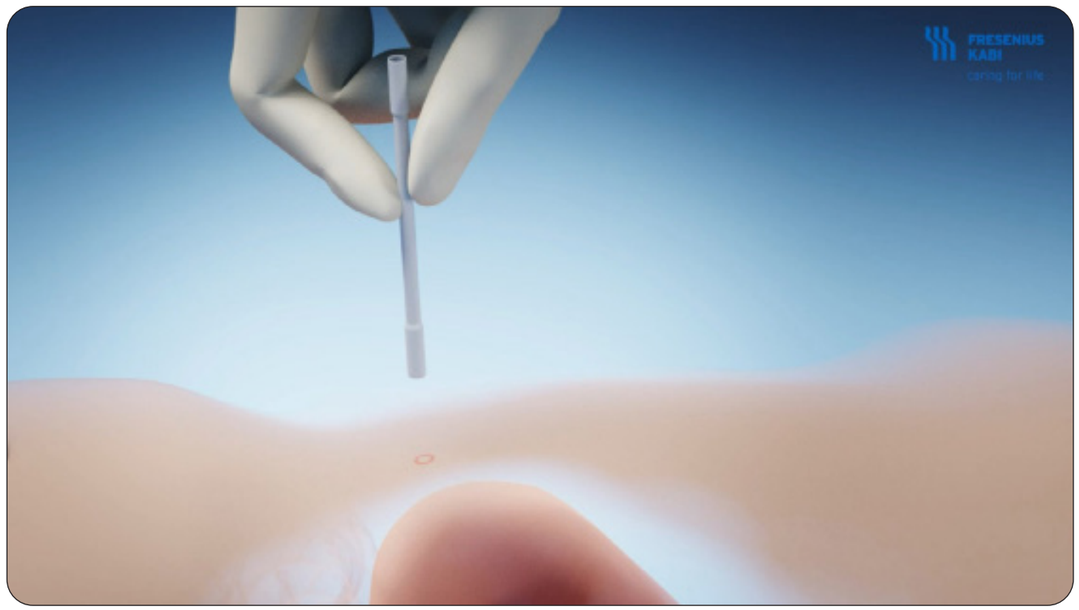


## Surgical technique

### Percutaneous endoscopic pull through method




The room is darkened and the appropriate puncture site determined by diaphanoscopy. The puncture site is checked by finger pressure from the outside.

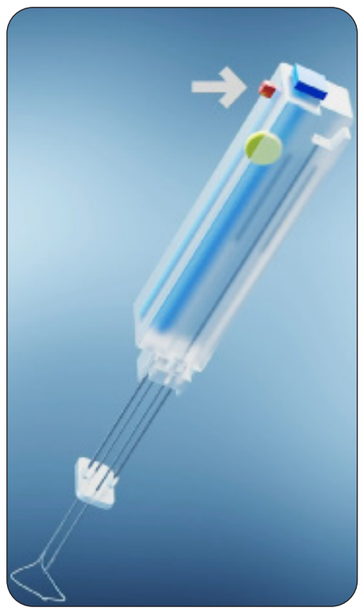



The puncture site is then marked. **NOTE: If you are using the gastropexy device to attach the gastric wall to the abdominal wall with sutures read on, otherwise skip ahead to page 14.**

## **Gastropexy device** option

### Testing the device before use

Press the blue trigger.  The fixation loop forms at the tip of the needle.

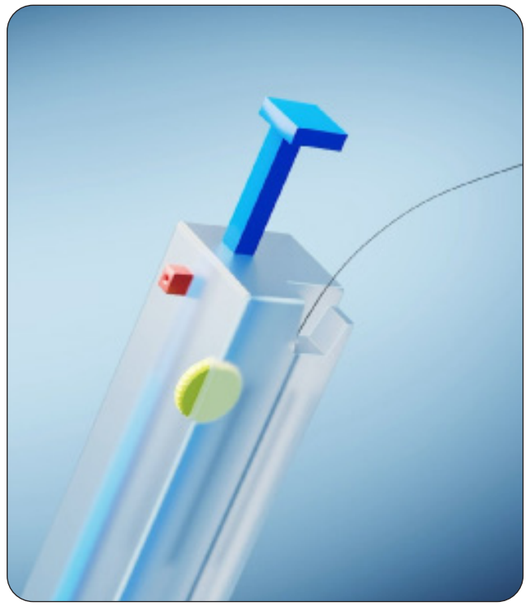


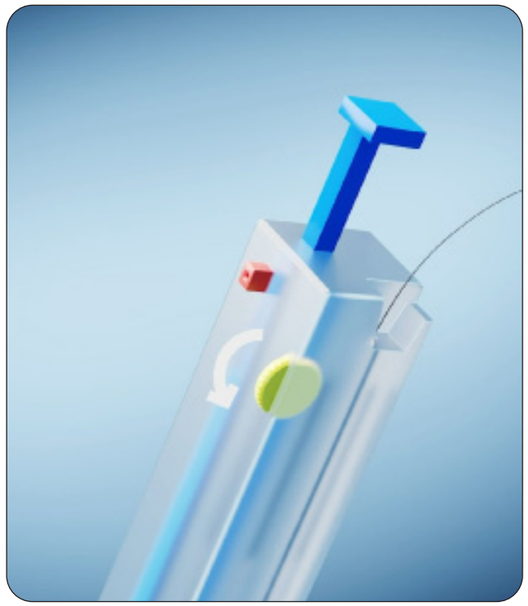
To retract the fixation loop back into the needle press the red button.  The fixation loop must remain inside the needle.  Check the yellow thread feed roller for smooth operation.



**Gastropexy device** option

### Testing the device before use





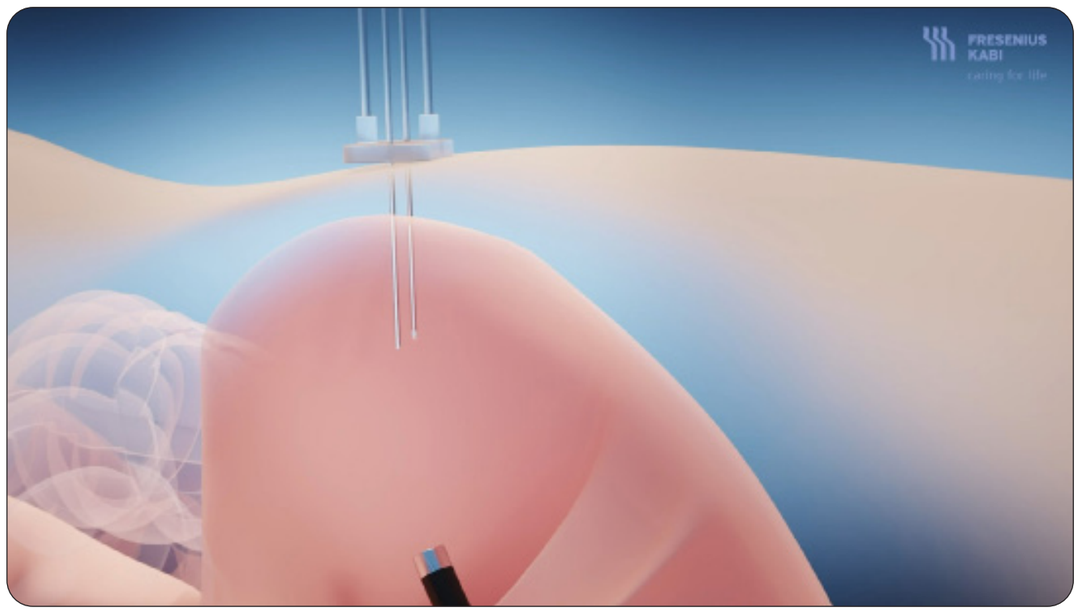
Push the suture material into the thread insertion opening until a slight resistance is felt.  To move it further turn the thread feed roller until the suture material reaches the tip of the needle.

The suture material must remain just inside the tip of the needle, retract if required using the yellow thread feed roller.

**Gastropexy device** option

## Percutaneous endoscopic pull through method

Position the guide plate to approximately 1 - 2 cm from the needle tip.  This is important as it allows parallel insertion of the needles.

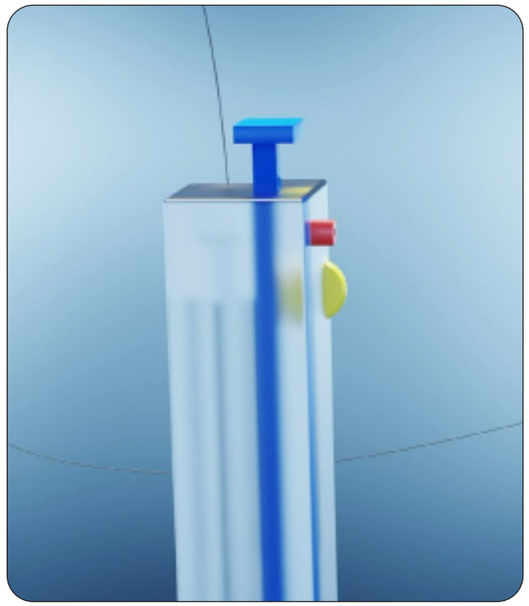


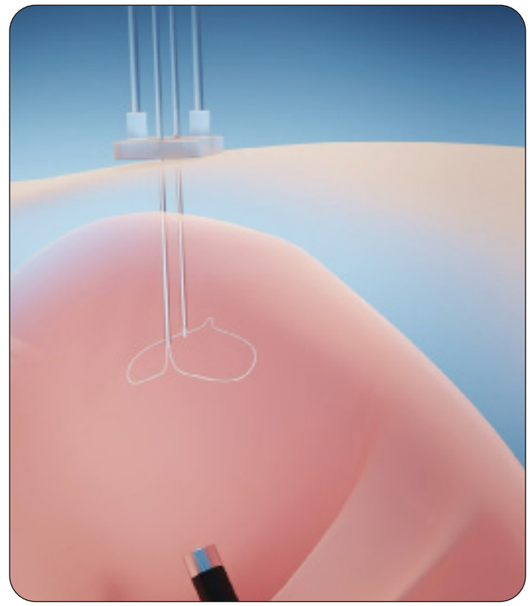

Carefully puncture the stomach with the gastropexy device at the marked site.  The two needles must remain parallel to each other during insertion.



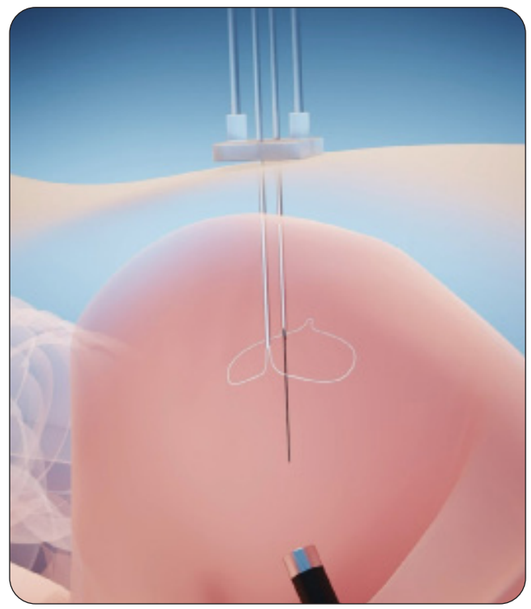
**Gastropexy device** option

## Percutaneous endoscopic pull through method



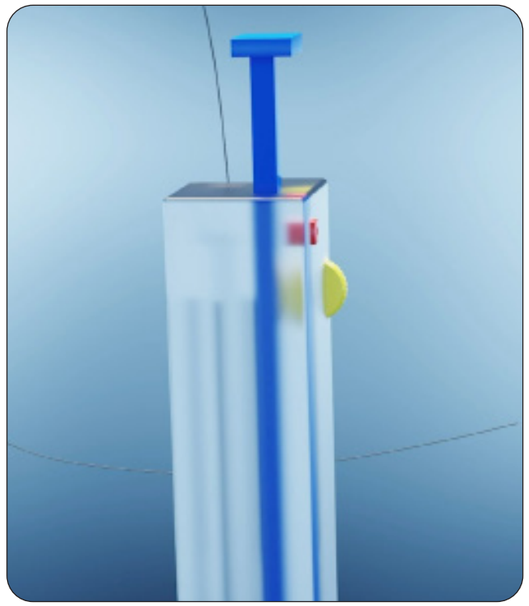


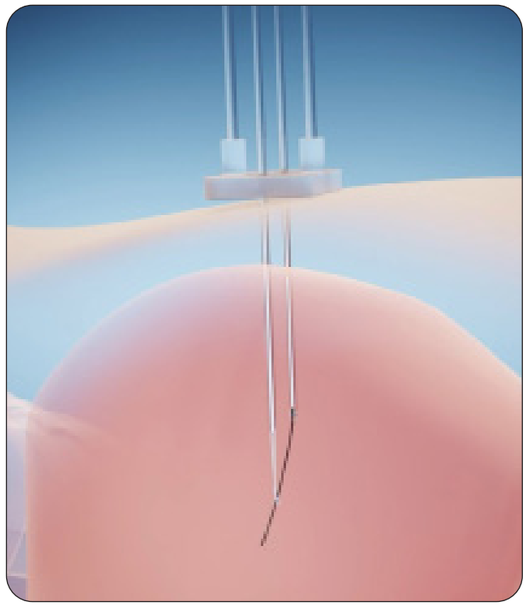
When approximately 15 - 20 mm of both needles are endoscopically visable the blue trigger is pressed so that the loop forms directly under the opposite needle.



The suture material can now be pushed into the stomach using the thread feed roller on the second needle.  Sufficient thread must be endoscopically visible in the stomach.

## Percutaneous endoscopic pull through method





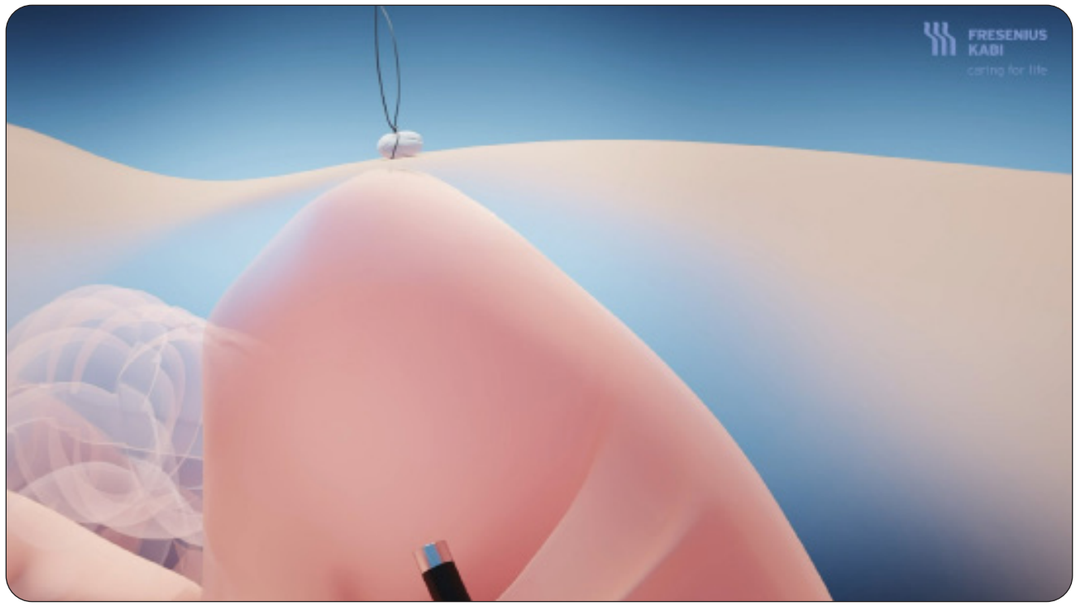
Press the red release button.  This attaches the suture material with the loop to the tip of the needle.  The loop must no longer protrude from the needle.


When it has been ensured that the suture material can run freely the entire gastropexy device is carefully pulled out of the stomach.

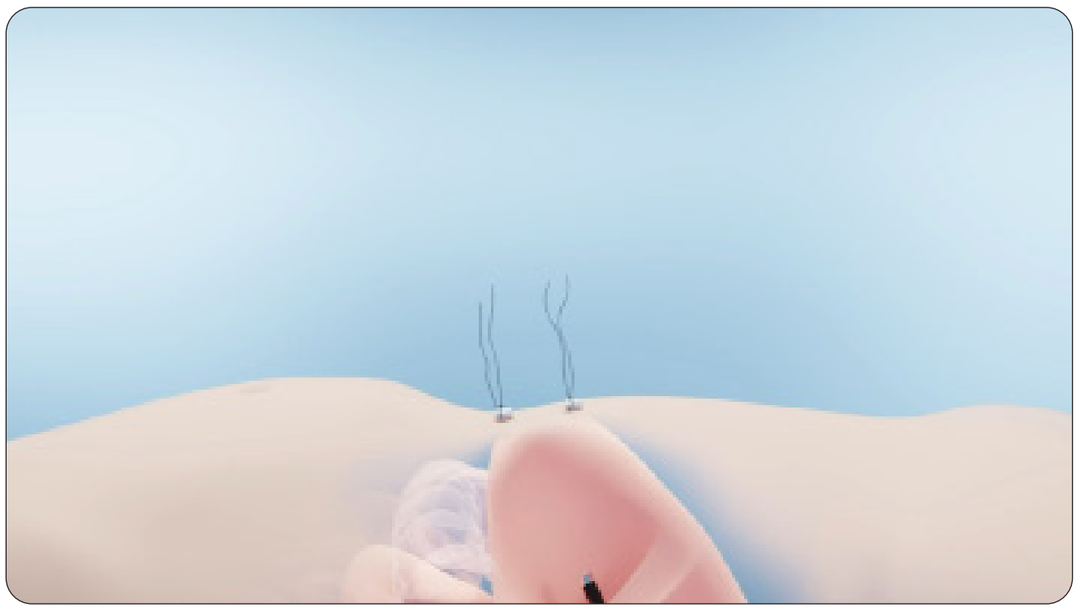


**Gastropexy device** option

## Percutaneous endoscopic pull through method



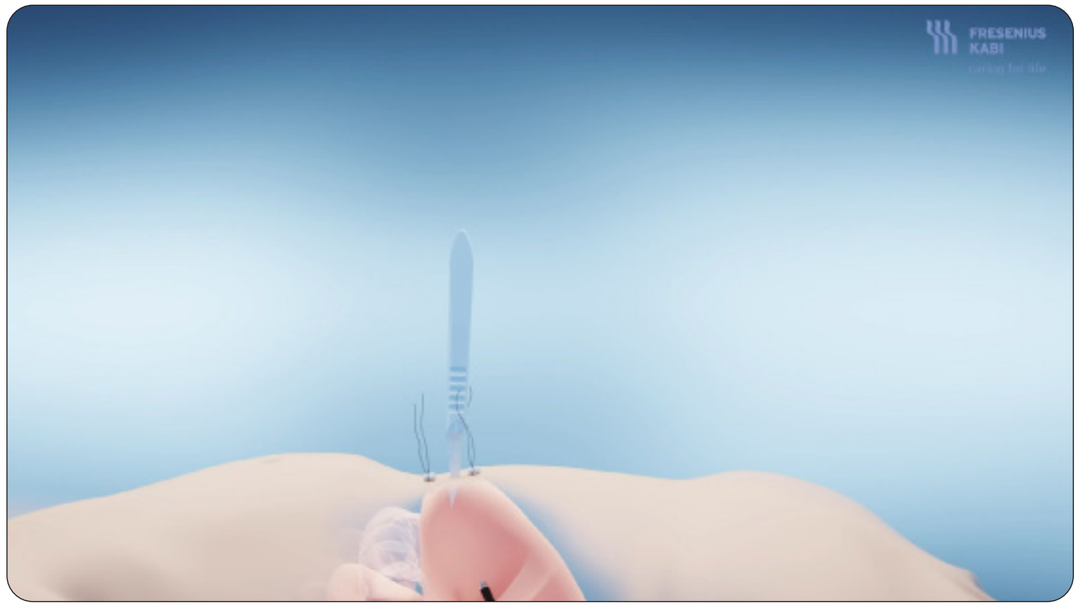

Place a cotton ball between the threads and tie them tightly into a knot.  Do not cut off the ends of the threads.  Cotton balls absorb secretions and buffer the threads in case of initial swelling.



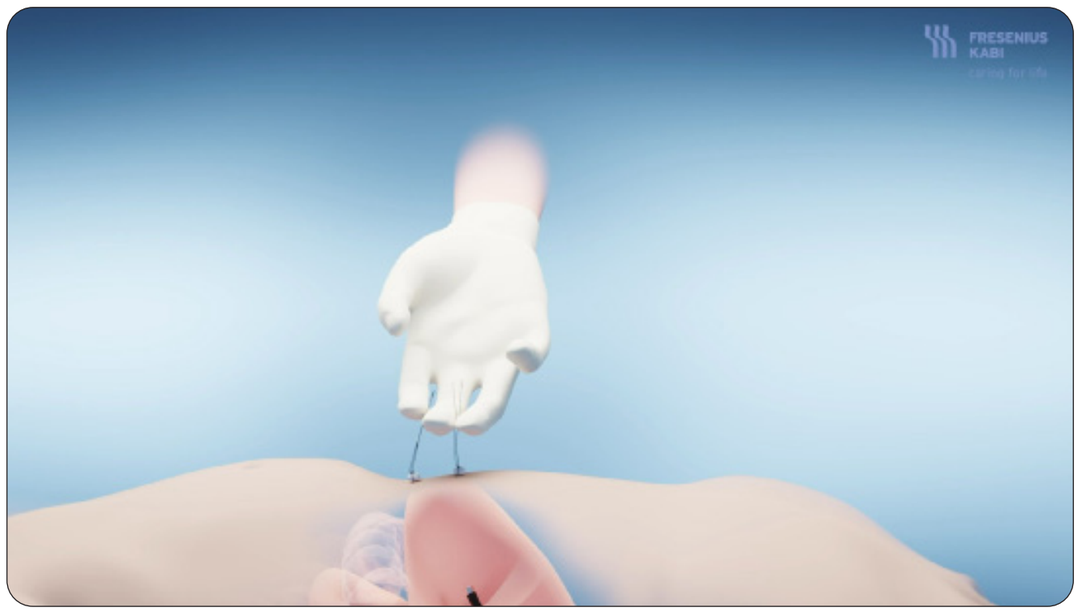
Repeat the procedure at least once, preferably twice more to properly secure the gastric wall to the abdominal wall.

**Gastropexy device** option

## Percutaneous endoscopic pull through method



The puncture site is located between the gastropexy sutures and a suitable stab incision made with the safety scalpel.



Pull on the sutures until the abdominal wall is lifted.

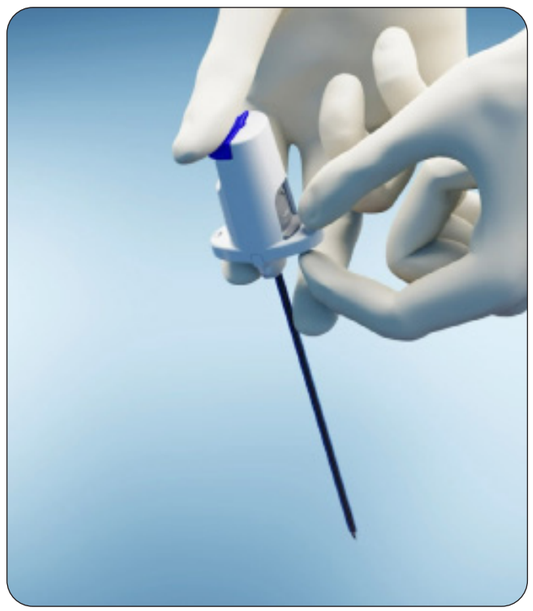
## Percutaneous endoscopic pull through method

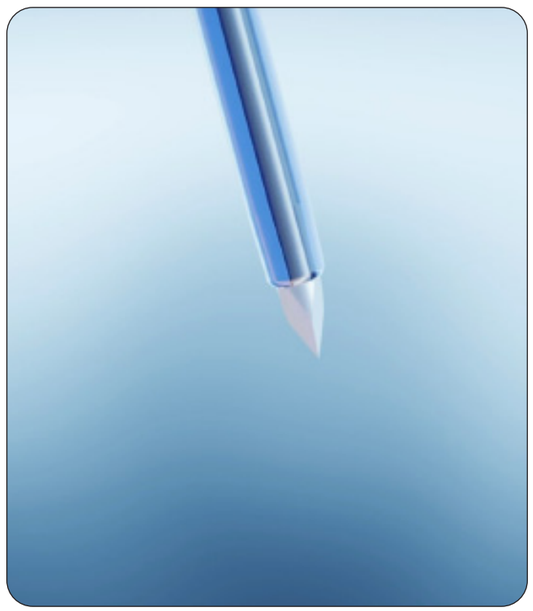
To protect against cuts, the trocar is locked in the basic position by a safety mechanism so that the cannula cannot be accidentally pushed forward.

Unlock the safety puncture cannula by pressing the grey unlock button.

## Percutaneous endoscopic pull through method

**NOTE:** If the unlock button is pressed in, the trocar is irreversibly unlocked and cannot be locked again.





Press the blue button to advance the trocar ready for puncture. **NOTE:** If the trocar is removed from the cannula, the needle guard automatically deploys and puncture is no longer possible.



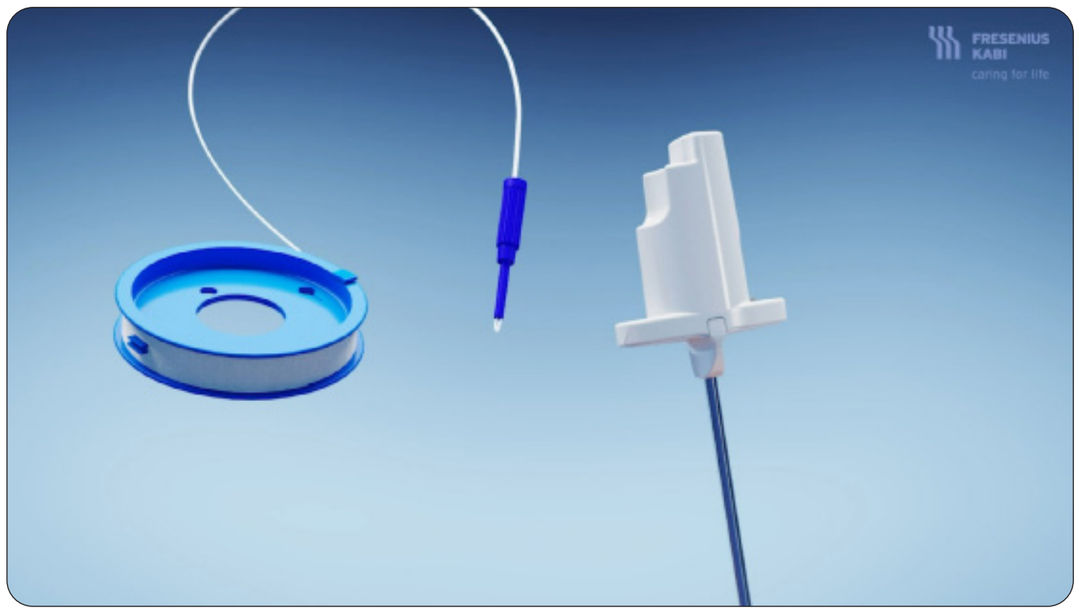
## Percutaneous endoscopic pull through method


The puncture cannula is inserted into the stomach under endoscopic control.


Secure the end of the puncture cannula with the endoscopy forceps.

## Percutaneous endoscopic pull through method

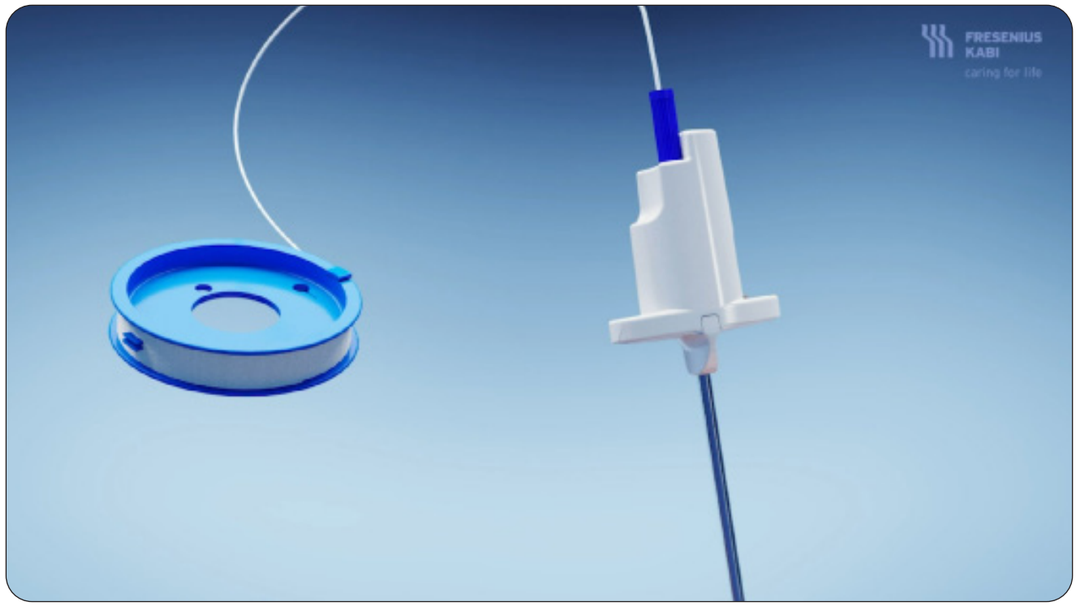

Remove the puncture needle from the cannula.



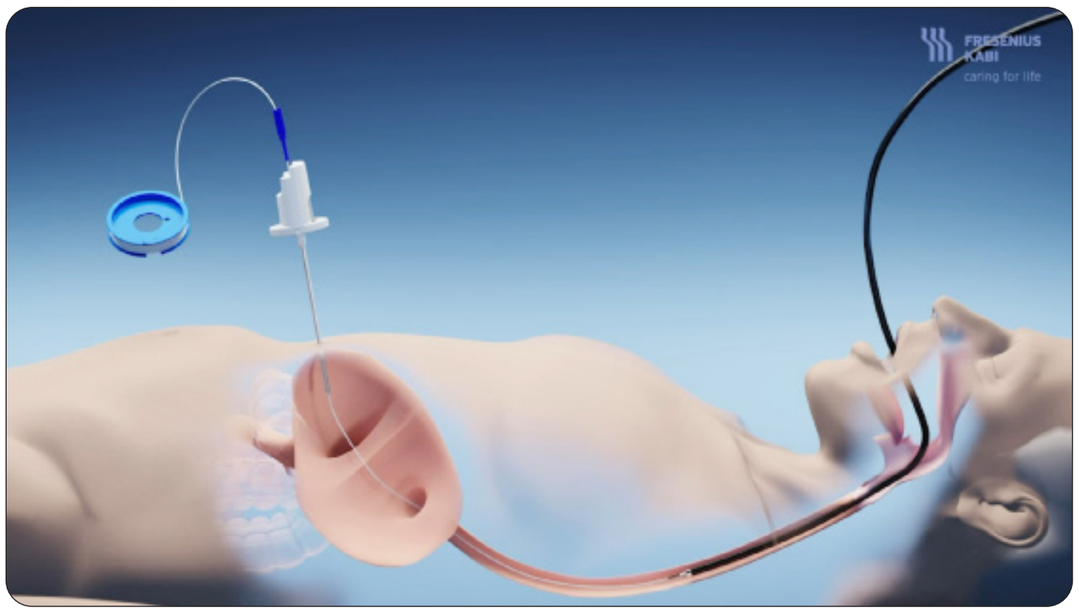

The blue insertion aid is pushed forward over the double thread until it only protrudes approximately 1 mm from the end.



## Percutaneous endoscopic pull through method

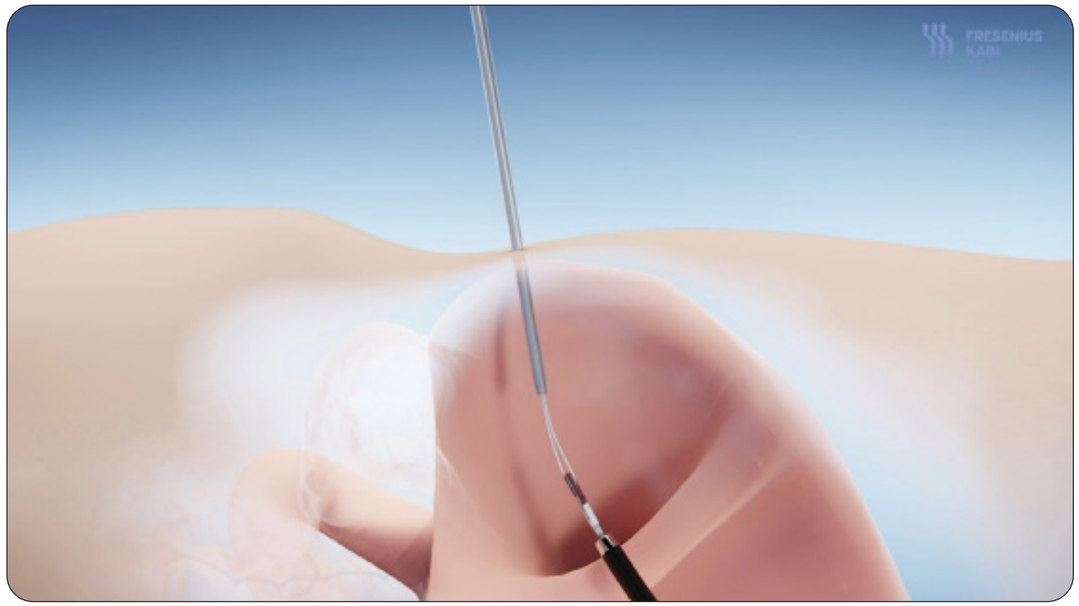



Place the insertion aid into the cannula.




Advance the thread into the stomach.

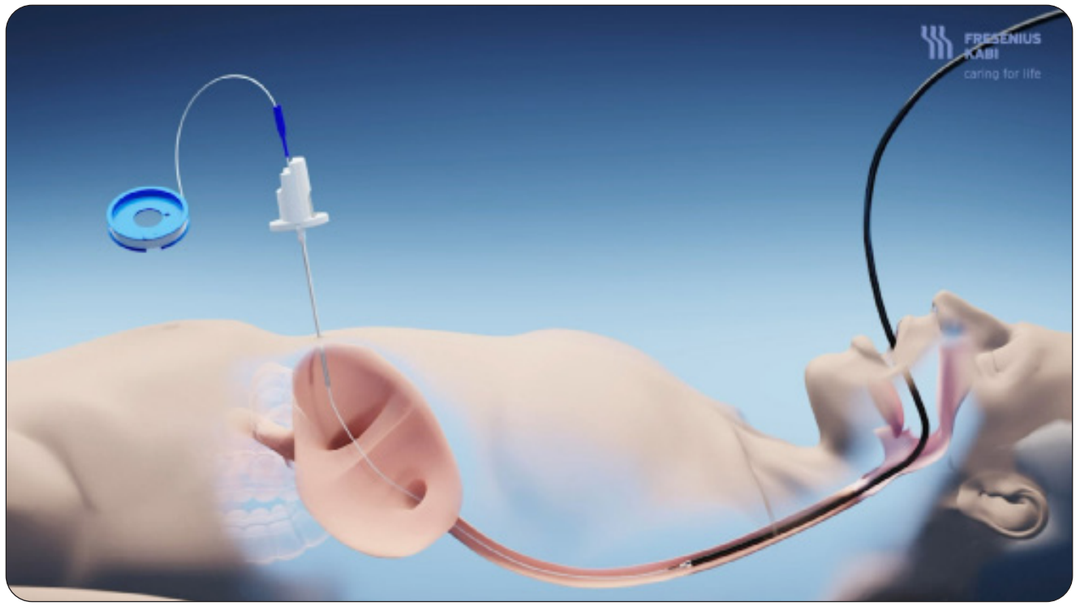
## Percutaneous endoscopic pull through method



Grasp the thread with the biopsy forceps.

Pull back the blue insertion aid on the thread.  The safety air valve on the cannula prevents the air in the stomach from escaping.

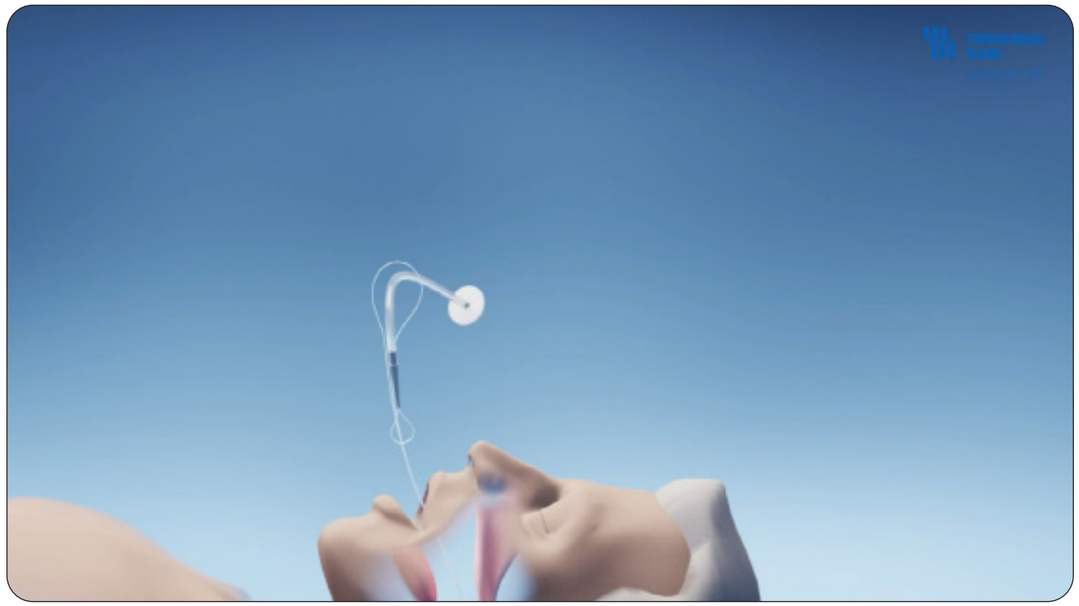
## Percutaneous endoscopic pull through method



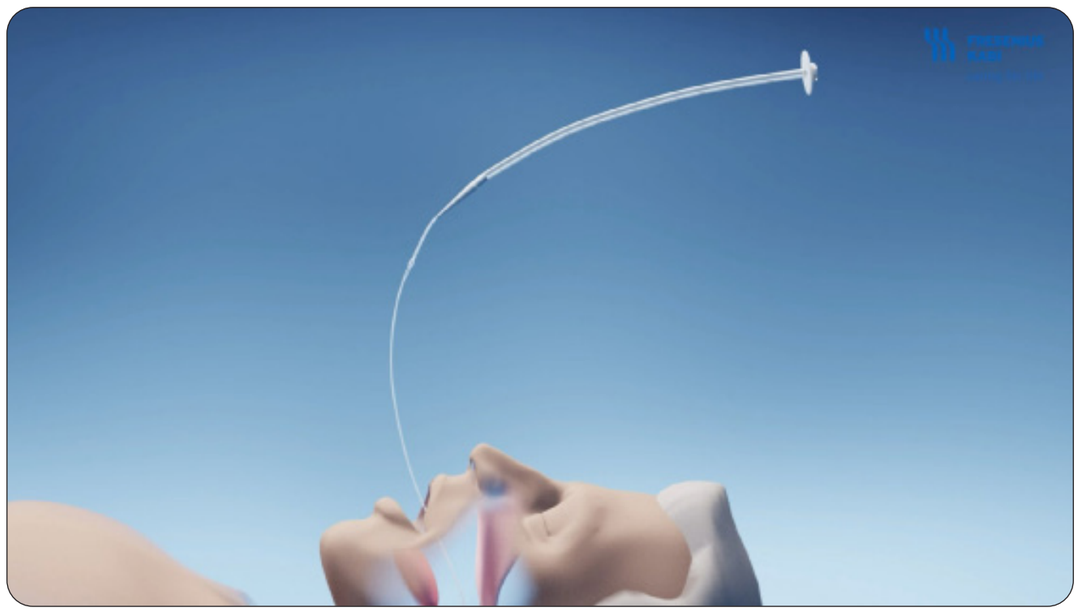
Pull out the thread together with the endoscope through the patients mouth.

Bring the loop of the double thread towards the fixation loop of the tube.

## Percutaneous endoscopic pull through method



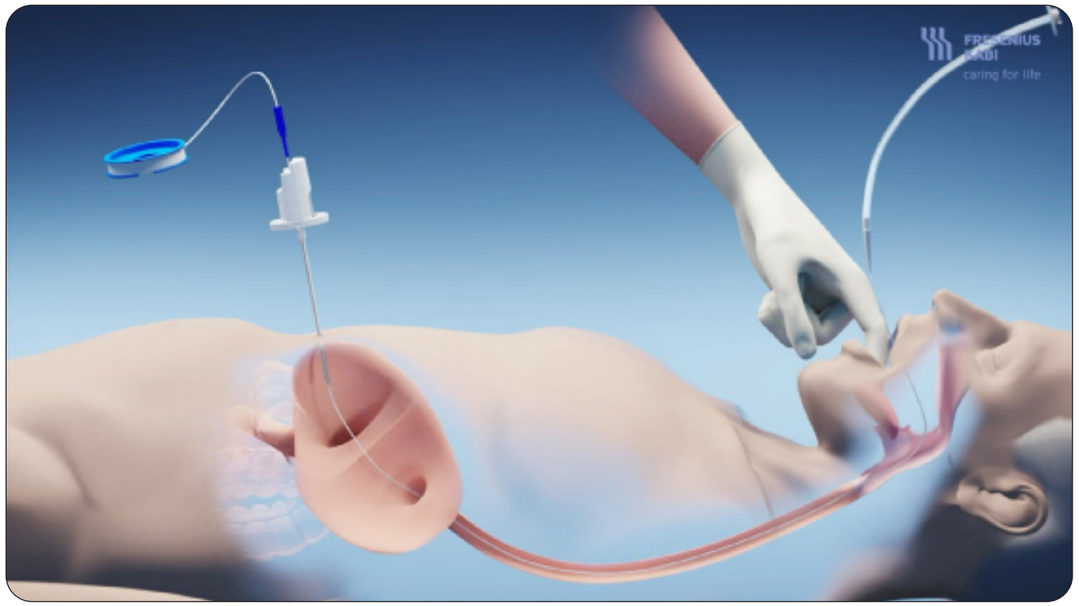
The loop of the double thread is attached to the fixation loop of the tube.



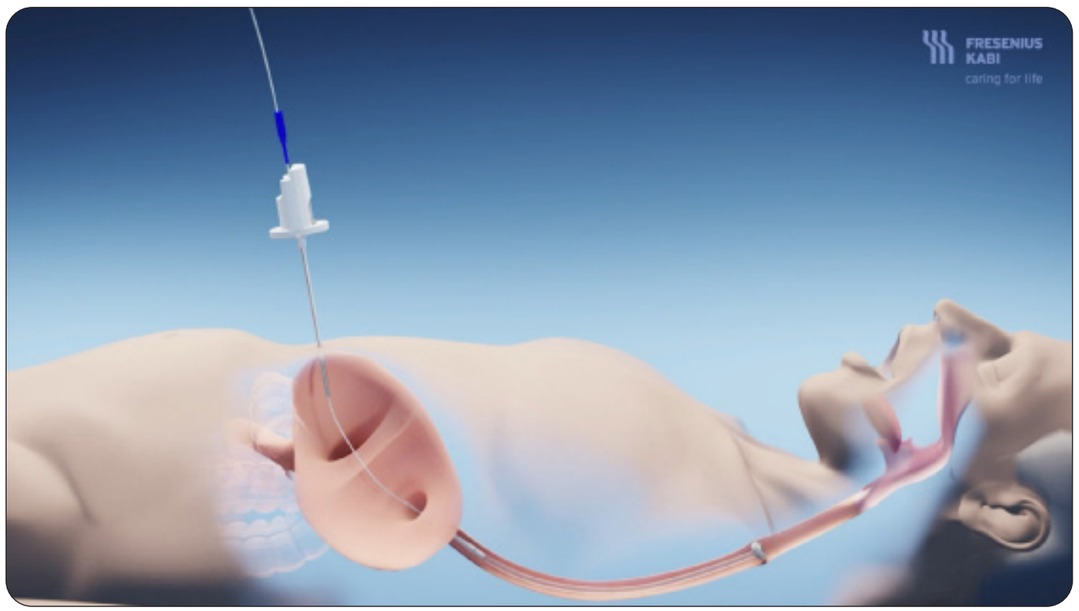
The tube is placed intragastrically by pulling on the distal end of the thread.



## Percutaneous endoscopic pull through method

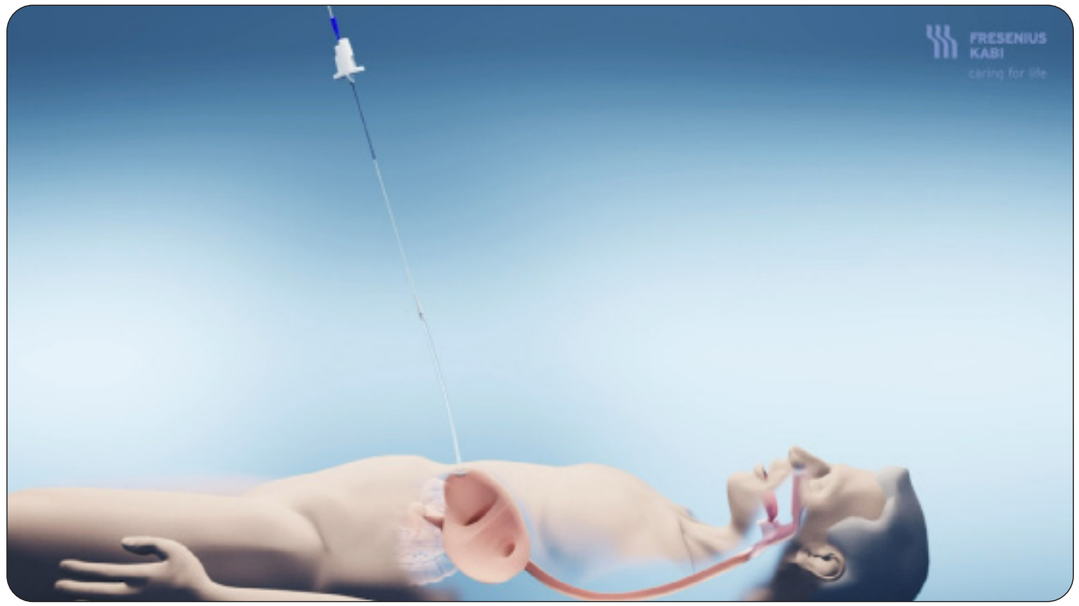



The tongue is pressed down laterally with a finger to avoid the thread from cutting in.




Guide the thread and the tube by hand while gently pulling on the distal end of the thread.

## Percutaneous endoscopic pull through method



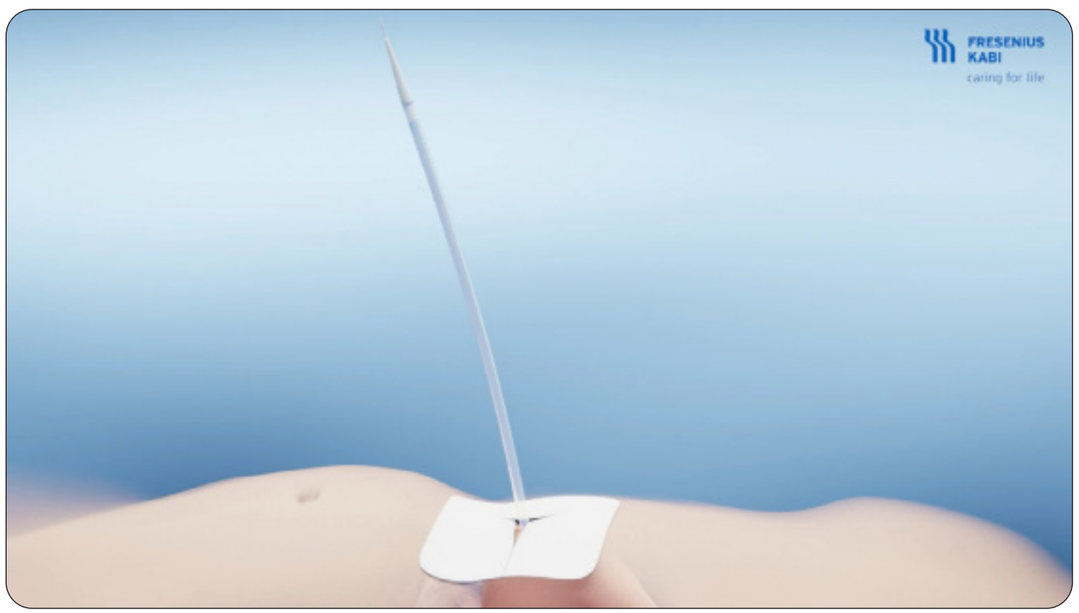

Resistance is felt when the tip of the tube enters the plastic cannula.  Remove the tube along with the plastic cannula outwards through the abdominal wall until the retention plate makes contact.


The thread of the tube is now cut off near the cone by sliding it into the safety scalpel.



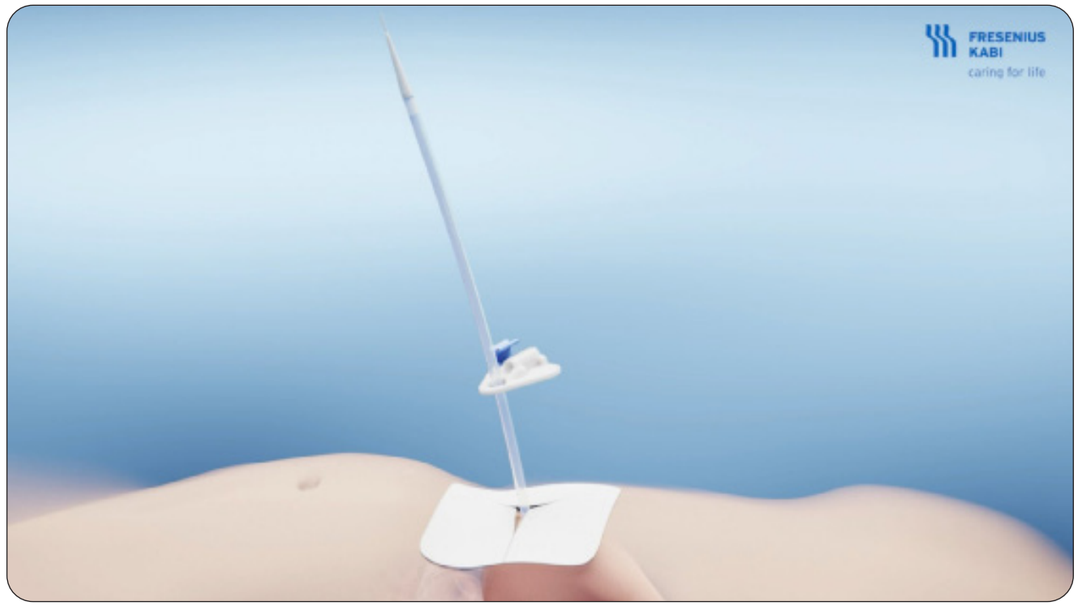
## Percutaneous endoscopic pull through method


The ends of the sutures can now be cut off if the gastropexy device was used.  Clean the puncture site and the tube well and dry them completely.




Place a sterile slip compress on the puncture site.

## Percutaneous endoscopic pull through method

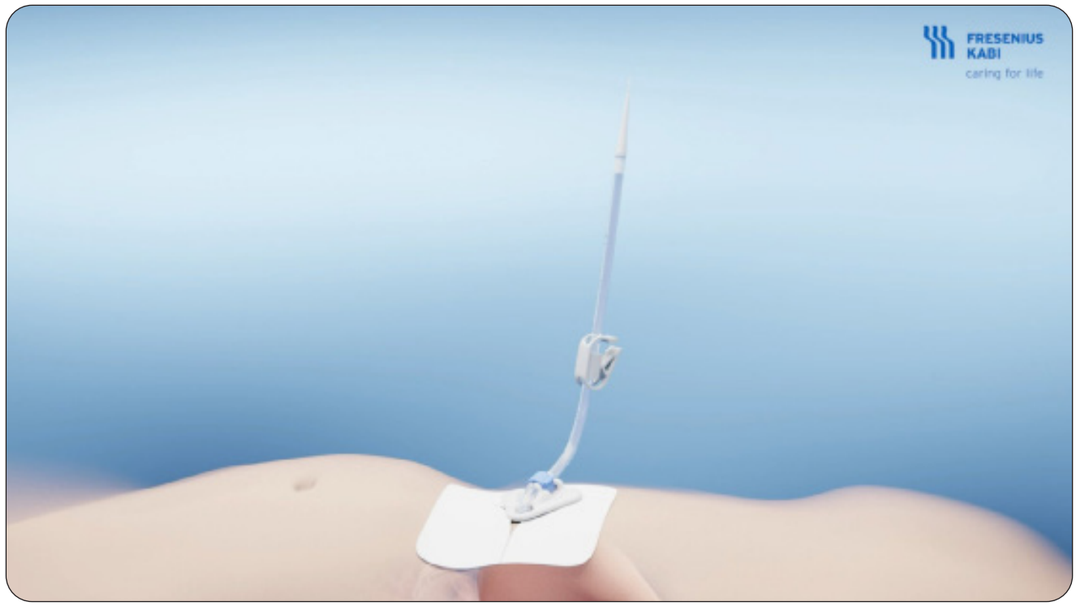



The outer retention plate is pulled over the tube.

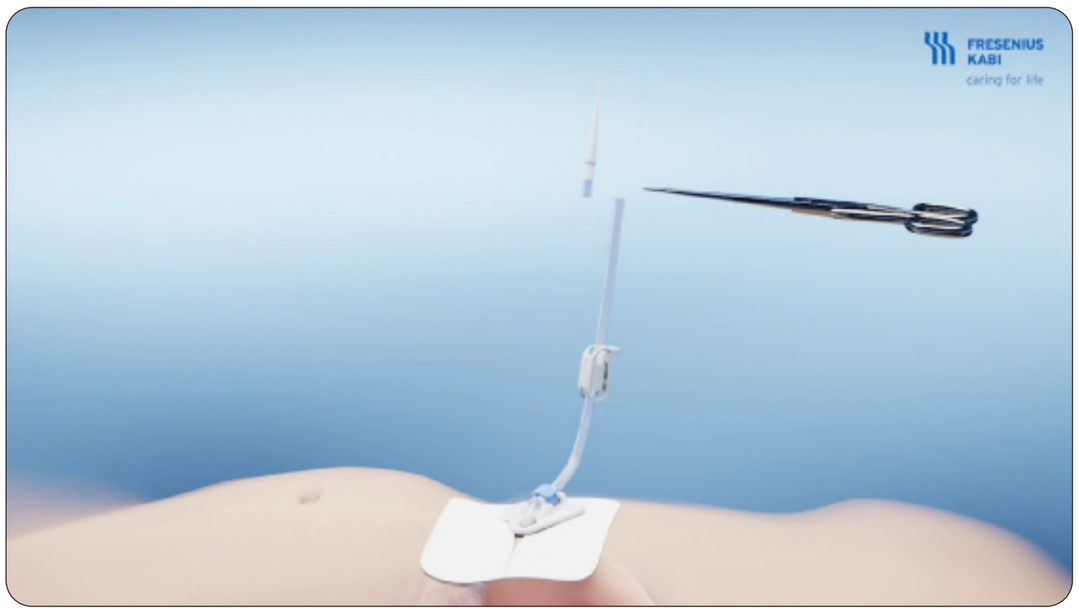

Tighten the tube until a slight resistance is felt.  Place the tube into the retention clamp and close the clamp securely.  **If the gastropexy device was used, tighten the tube with less resistance.**



## Percutaneous endoscopic pull through method



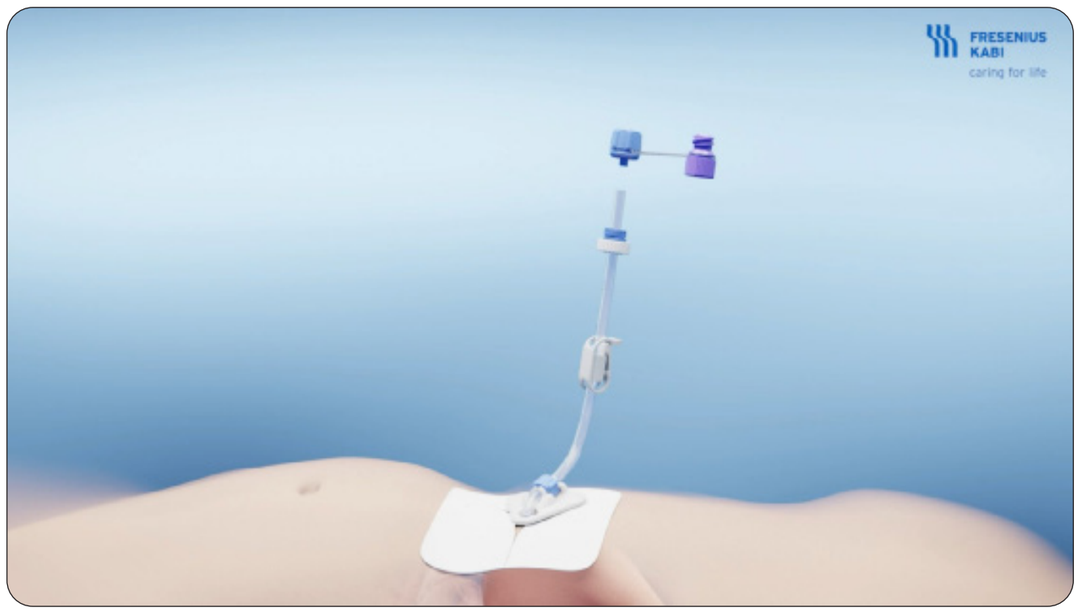

Place the tube clamp onto the tube and close the clamp.




Cut off the cone of the tube.  Do not cut too short leaving enough tube length for later connecting the ENFit connection.

## Percutaneous endoscopic pull through method

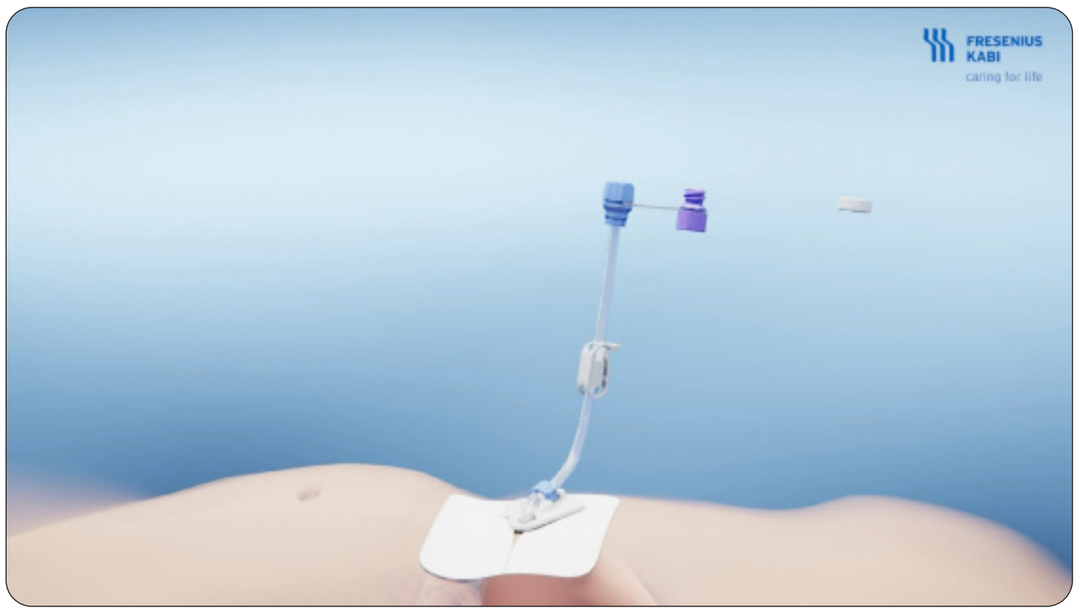

Place the fastening screw for the ENFit connector over the tube.




Push the ENFit connector pin into the tube as far as possible

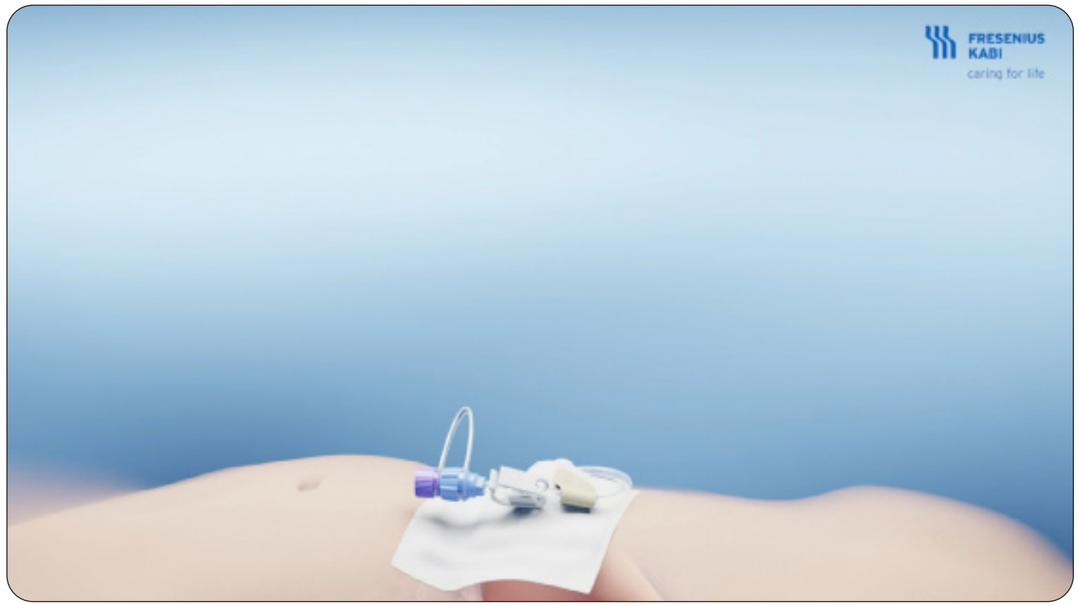
## Percutaneous endoscopic pull through method


Secure the fastening screw to the ENFit connector.




Pull the screw aid downwards and remove.

## Percutaneous endoscopic pull through method




Close the ENFit connector cap and open the clamp.

Cover the exit point of the PEG Pro tube with sterile dressings.

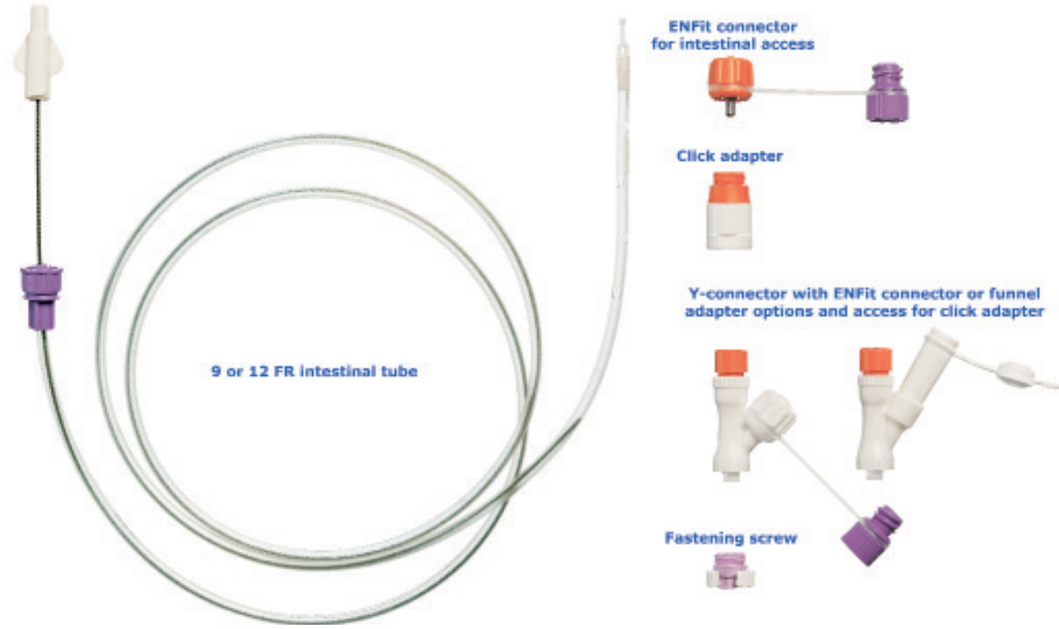
Dressing kits are available from Fresenius Kabi for this purpose.

Careful aftercare and daily maintenance of the Freka PEG Pro tube must be carried out according to the instructions for use.

**While it has been the objective of Fresenius Kabi to develop accurate, easy-to-follow insertion suggestions, each healthcare professional inserting the enteral product must evaluate the appropriateness of the following technique based on his or her medical training, experience and patient evaluation.**



## **Kit contents:** Intestinal tube for Freka PEG Pro 16 FR or 20 FR




### Freka intestinal 9 FR or 12 FR tube

- 120 cm polyurethane intestinal tube
- radiopaque markings every 5 cm
- teflon coated guidewire
- 9 FR for use with Freka PEG Pro 16 FR or 12 FR for use with Freka PEG Pro 20 FR.

### Freka ENFit connector

Integral cap. ENFit.  Connects to the click adapter.

### Click adapter

Used to connect the ENFit connector to the Y-connector.

### Y-connector

Connects to the Freka PEG Pro tube and provides **two options**:

- funnel connection for gastric acces
- ENFit connection for gastric access

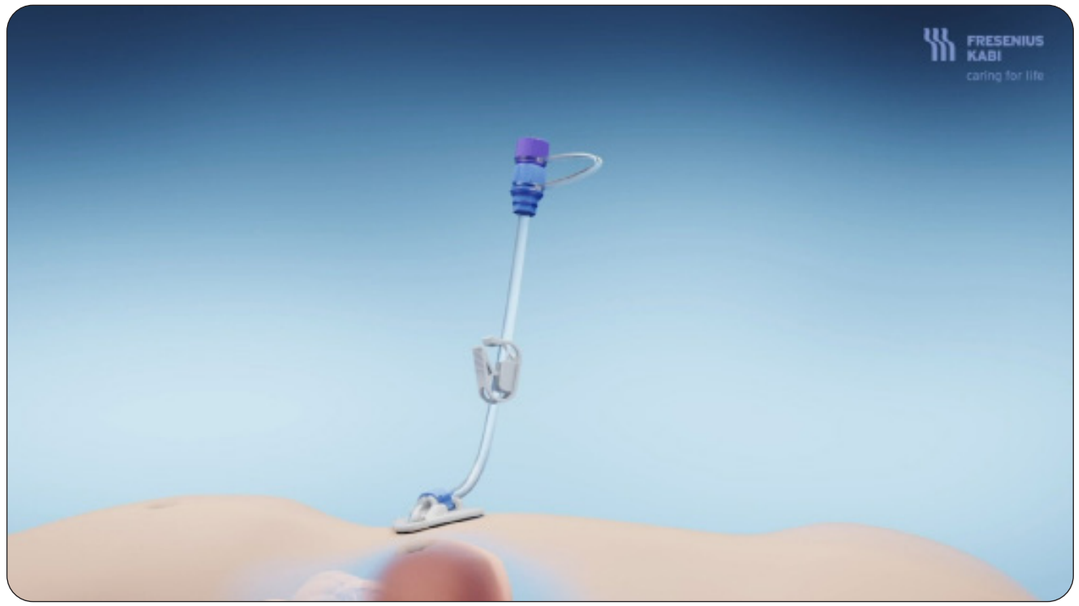
Both options have ENFit connections for intestinal access.

### Fastening screw

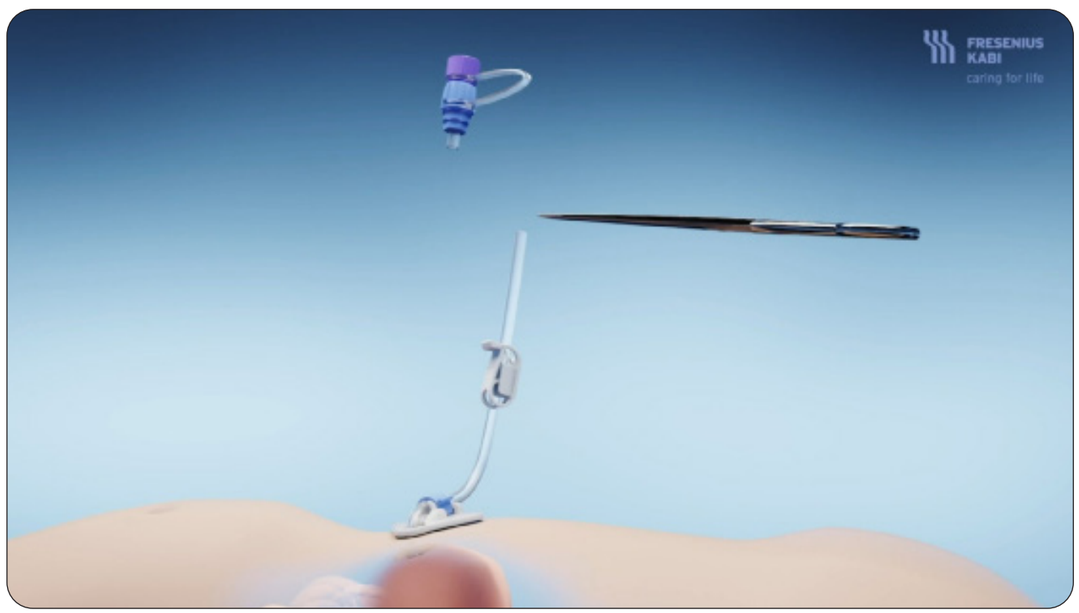
Secures the Y-connector to the Freka PEG Pro tube.

# Surgical technique

## Insertion of feeding tube into Freka PEG Pro endoscopically




Before inserting a Freka intestinal tube a Freka PEG Pro must be placed according to the instructions for use.  The Freka PEG tube serves as a guiding tube for the intestinal tube.




The tube clamp of the existing Freka PEG Pro is closed and the ENFit connector cut off and removed.



## Insertion of feeding tube into Freka PEG Pro endoscopically


The fixation screw for the Y-connector is placed over the tube.


The pin of the Y-connector is inserted as far as possible into the tube.  Choose either the gastric funnel or ENFit Y-connector as two options are available in the insertion kit.

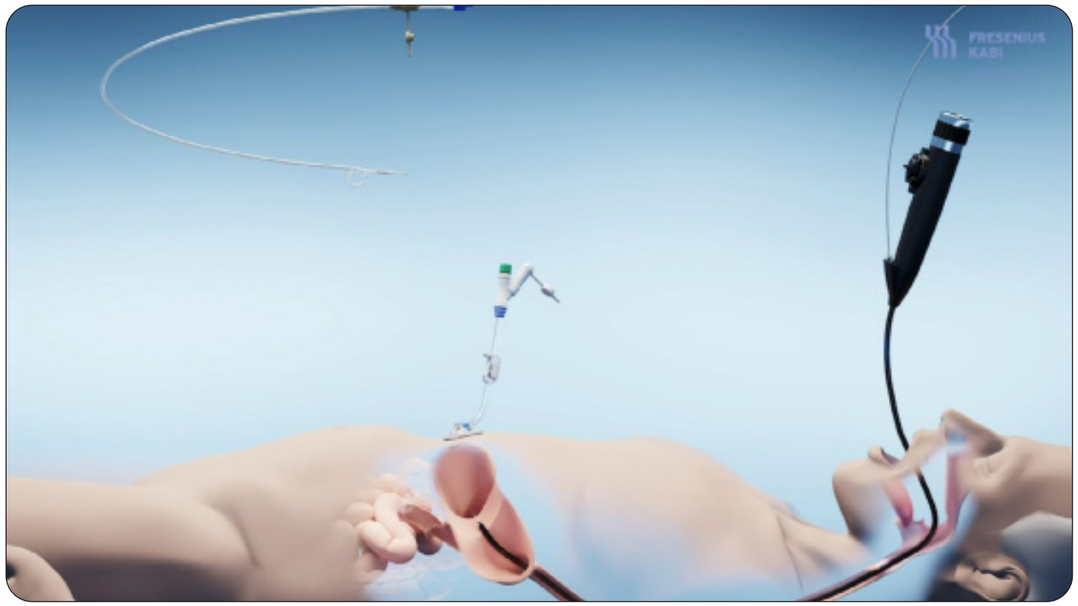
## Insertion of feeding tube into Freka PEG Pro endoscopically


The fixation screw is firmly screwed into the Y-connector.

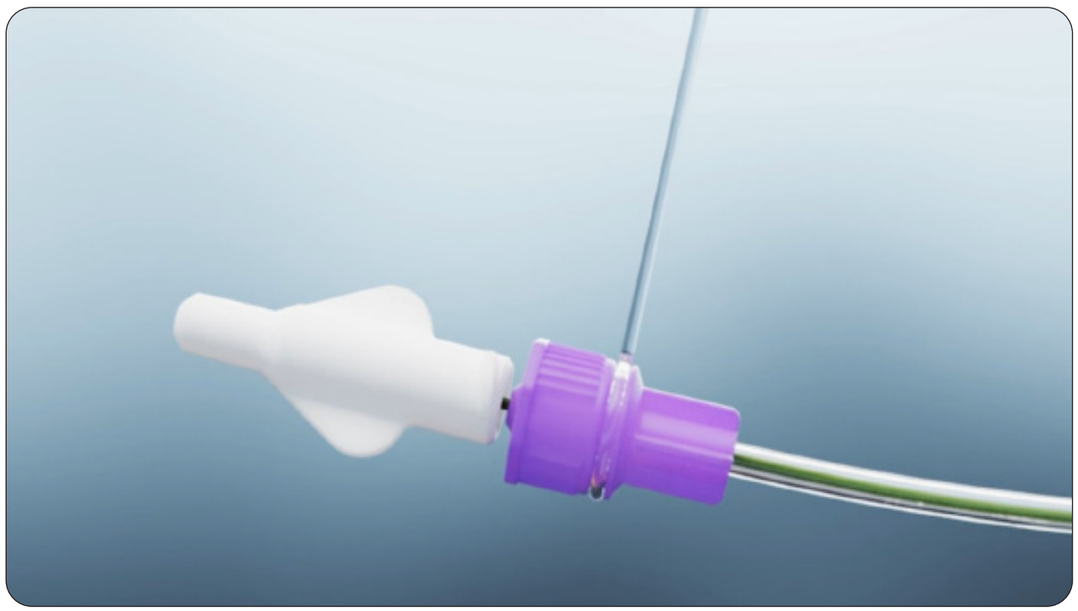

Pull the screw aid downwards and remove.



## Insertion of feeding tube into Freka PEG Pro endoscopically

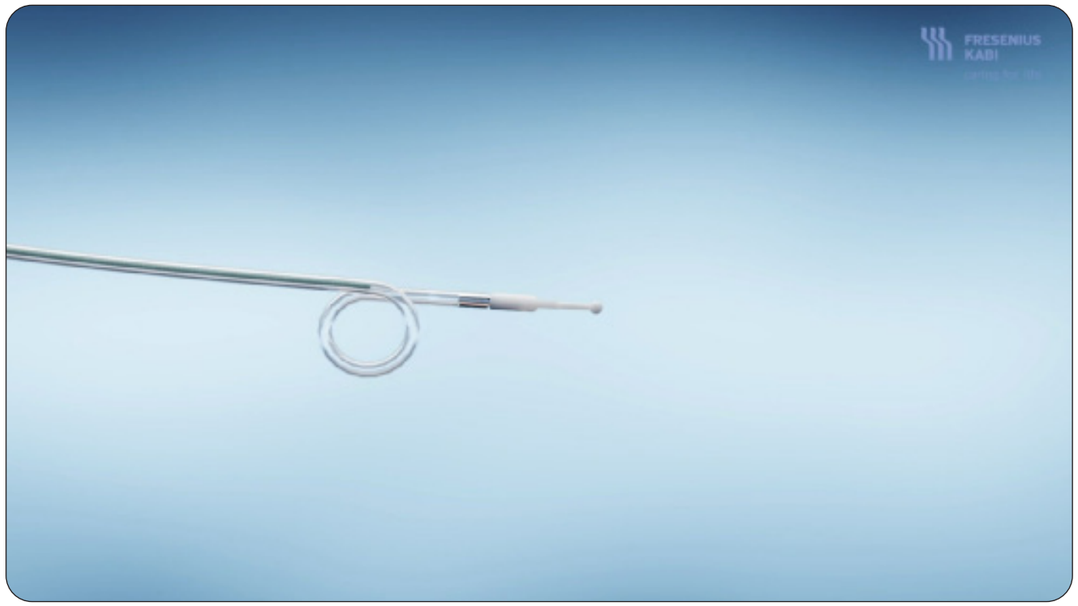



The endoscope is now inserted and the stomach insufflated.

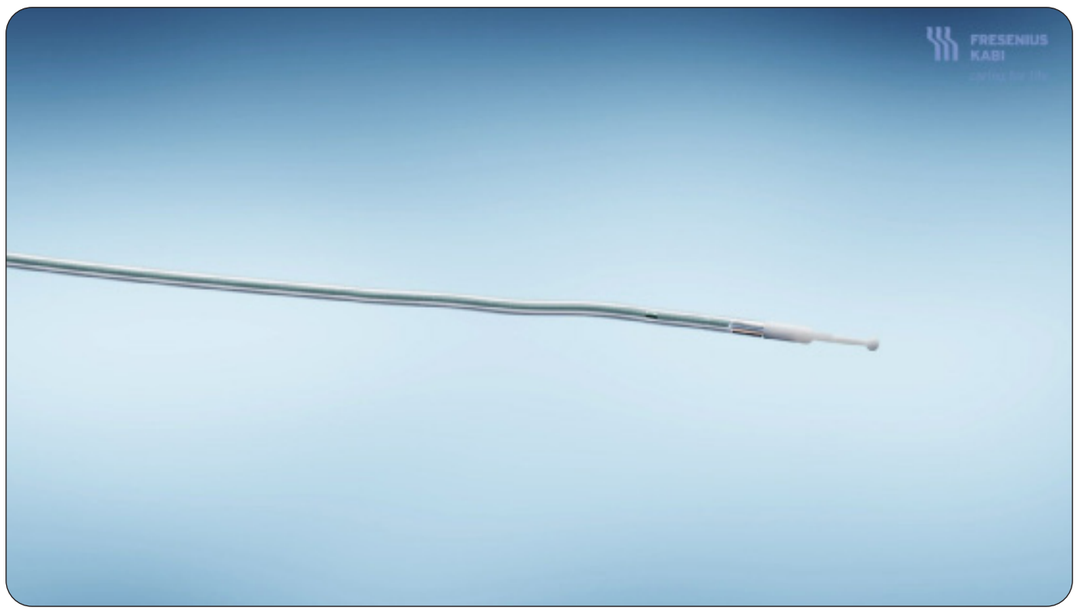


Next, use the mandrin to stiffen the intestinal tube.

## Insertion of feeding tube into Freka PEG Pro endoscopically



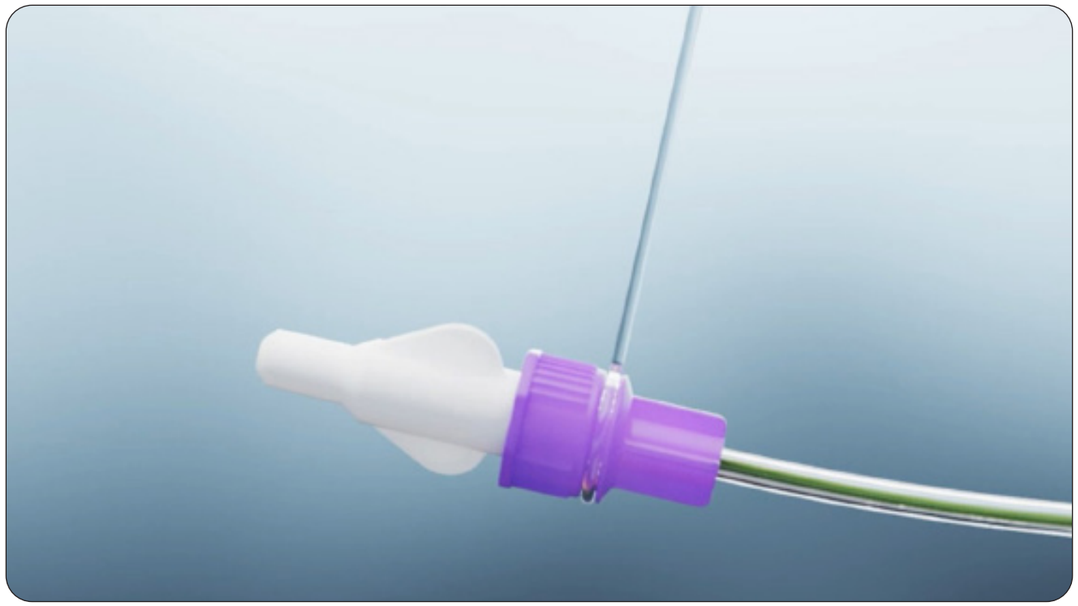

Advance the mandrin within the feeding tube.




Stop advancing the mandrin just before the metal ring at the end of the feeding tube.



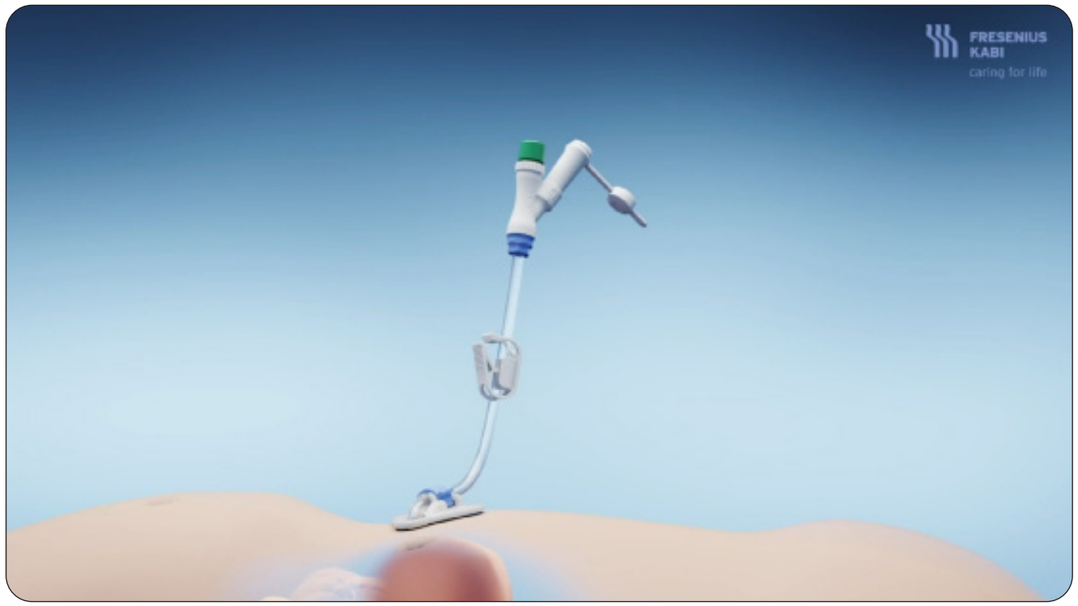
## Insertion of feeding tube into Freka PEG Pro endoscopically



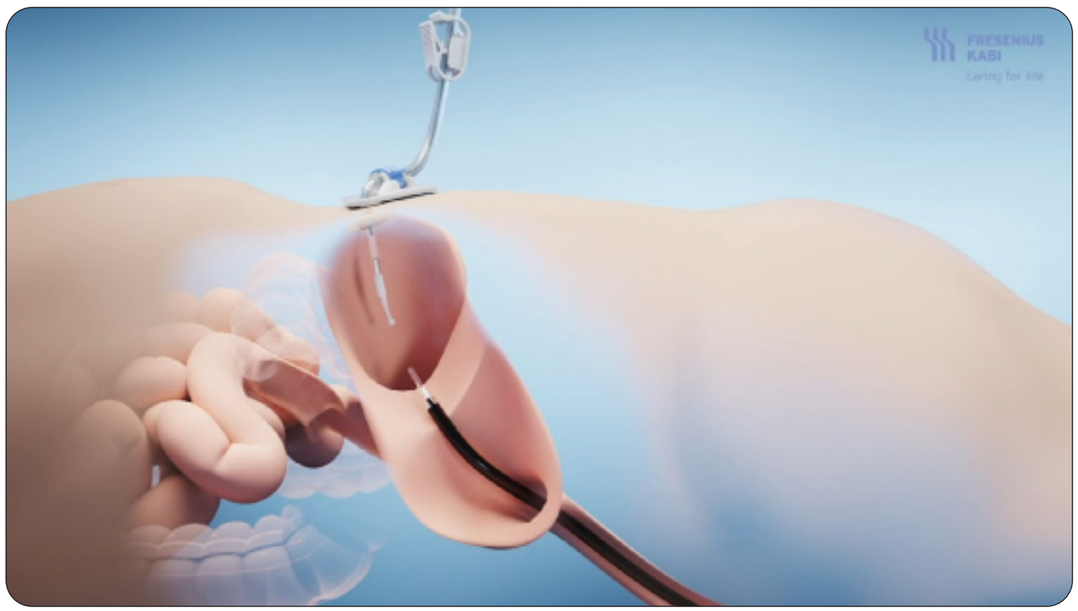
Secure the mandrin again by rotating the white fixing screw.


To make it easier to insert the intestinal tube the tube tip can be moistened with sterile water.

## Insertion of feeding tube into Freka PEG Pro endoscopically



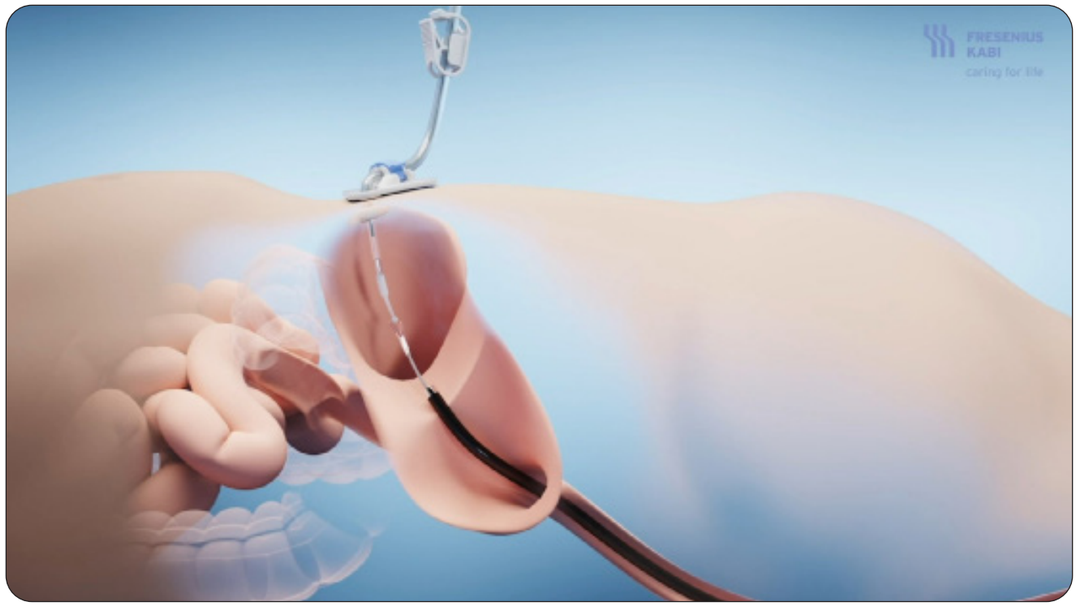

Open the tube clamp on the Freka gastic PEG Pro.



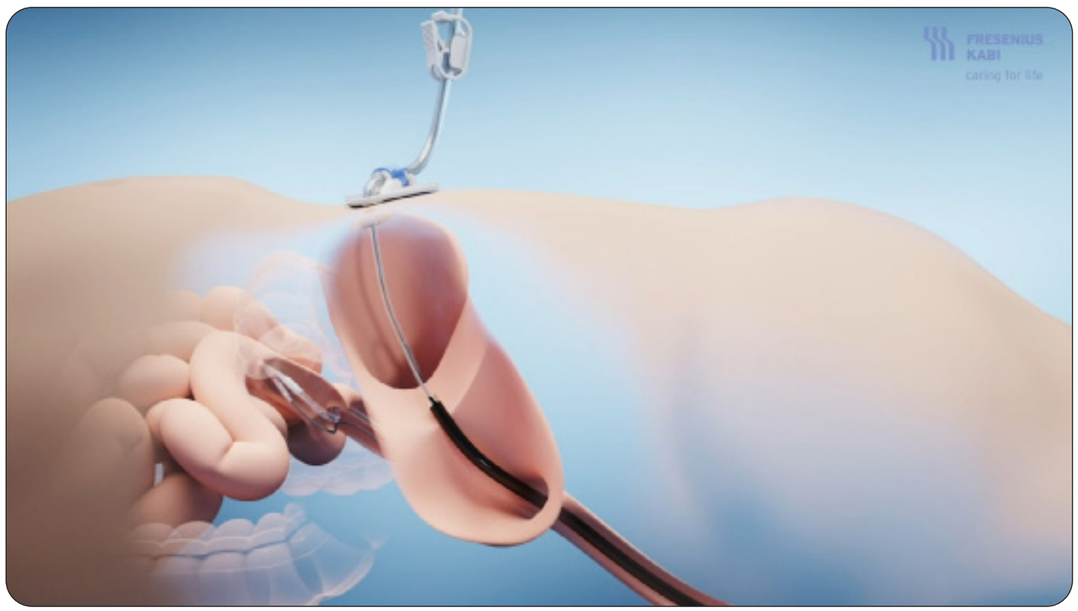

The intestinal tube is then carefully pushed through the straight access port of the Y-connector into the stomach.



## Insertion of feeding tube into Freka PEG Pro endoscopically

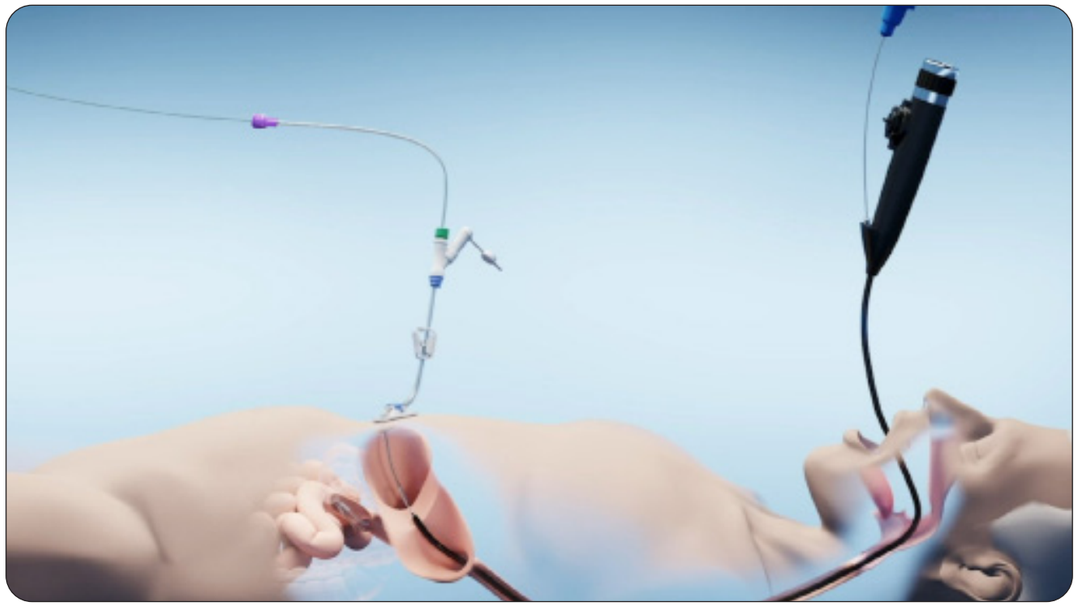



Grasp the tip of the intestinal tube with the forceps.




Pull the intestinal tube through the gastric lumen into the jejunum to behind the ligament of Treitz.

## Insertion of feeding tube into Freka PEG Pro endoscopically

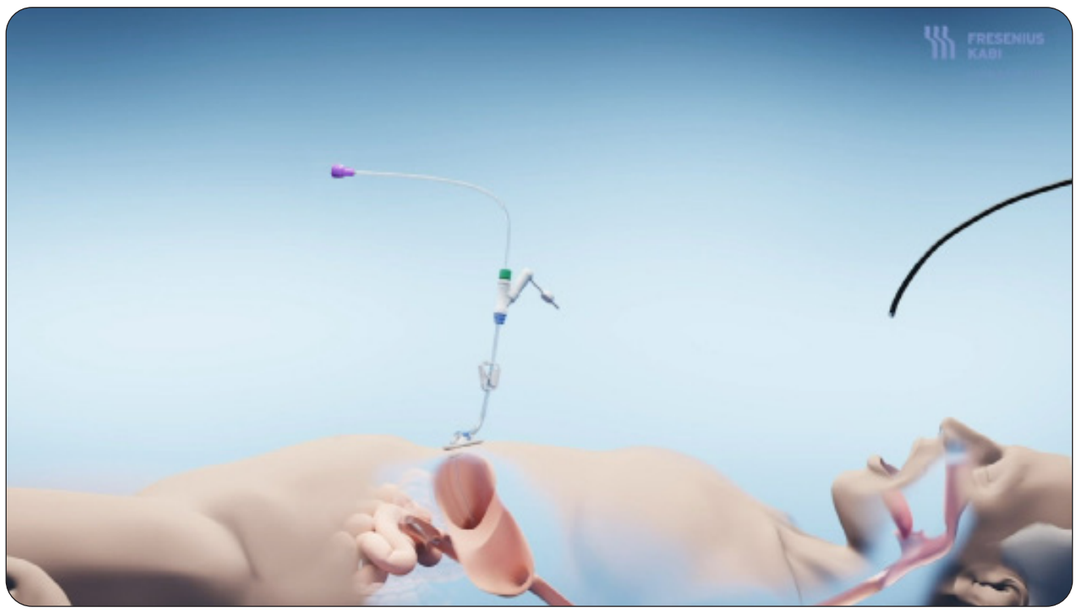


Once the desired position has been reached, the mandrin with the attached assembly is removed.

The intestinal tube is still held in place with the endoscopy forceps.

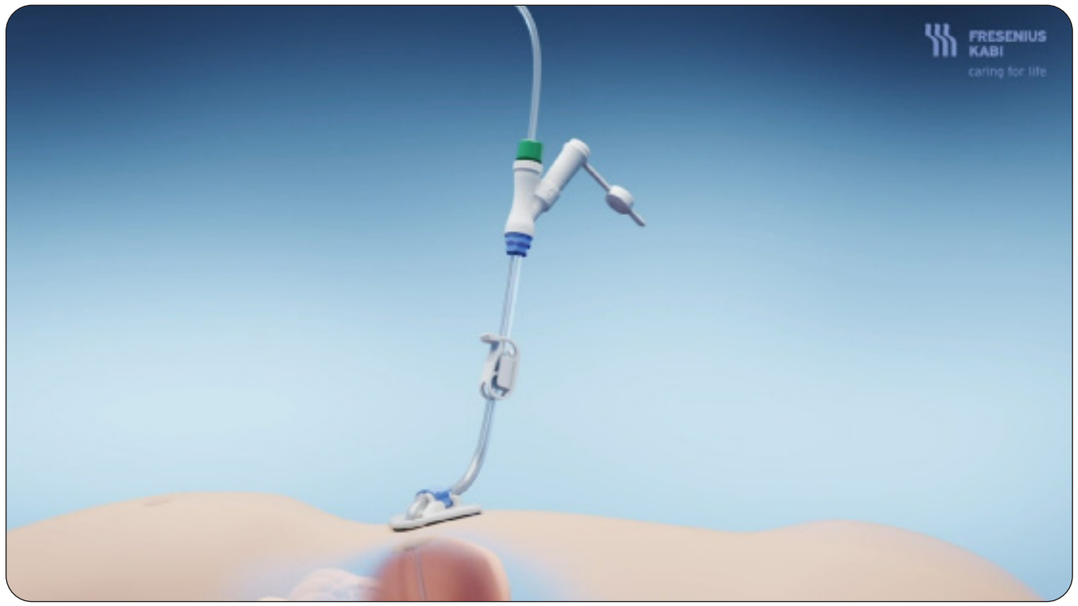
## Insertion of feeding tube into Freka PEG Pro endoscopically

The forceps are now disengaged from the intestinal tube.

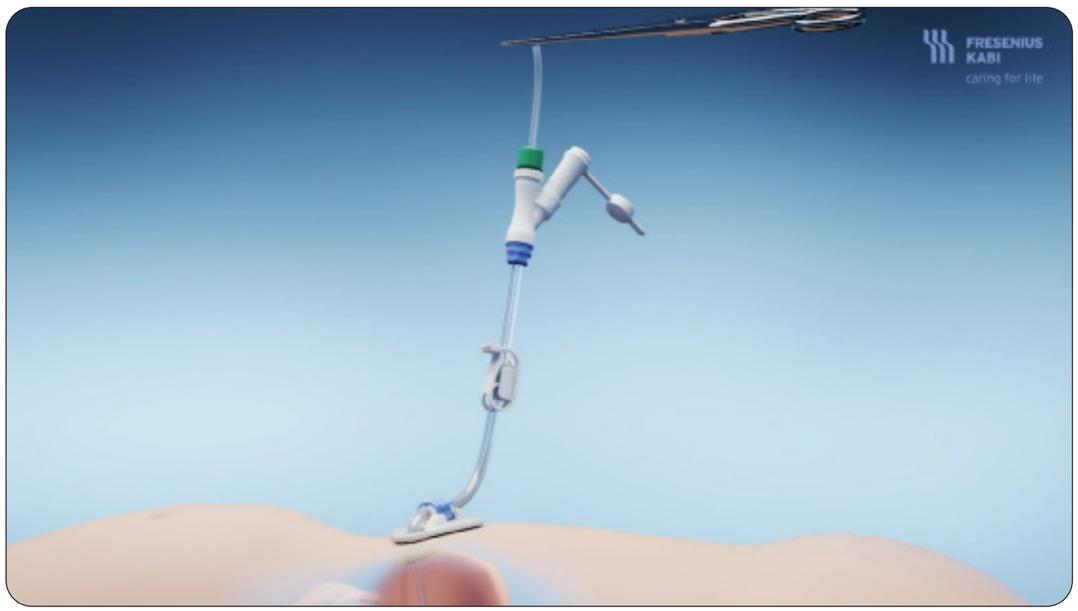


The intestinal tube and forceps are now fully removed from the patient.

## Insertion of feeding tube into Freka PEG Pro endoscopically




Close the tube clamp.




Cut the intestinal tube slightly above its exit from the Y-connector.



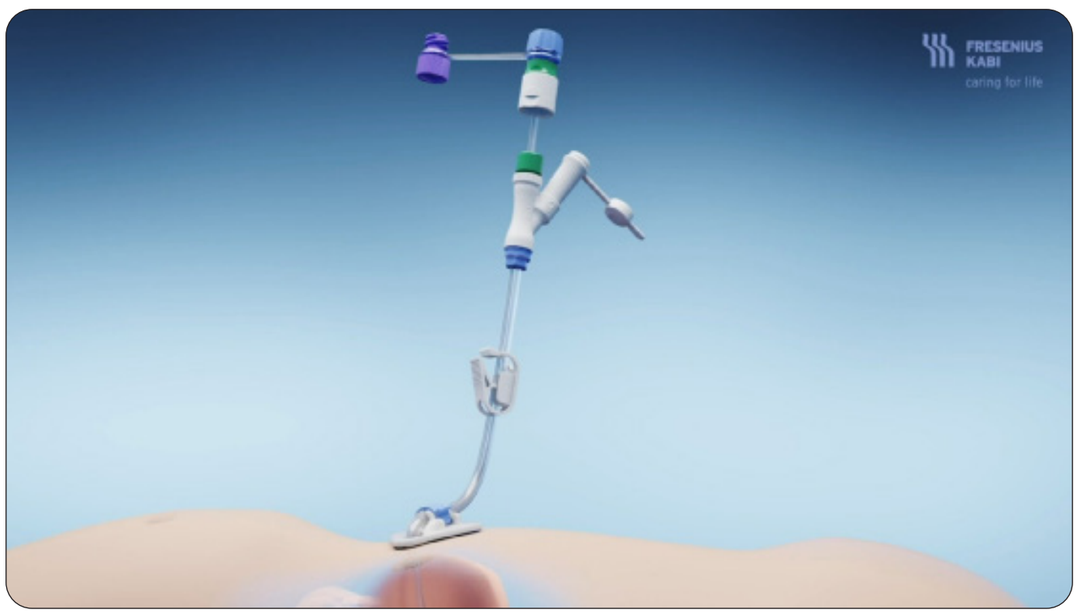
## Insertion of feeding tube into Freka PEG Pro endoscopically


Slide the click connector over the tube.


Push the metal pin of the ENFit connector into the tube as far as possible.

## Insertion of feeding tube into Freka PEG Pro endoscopically

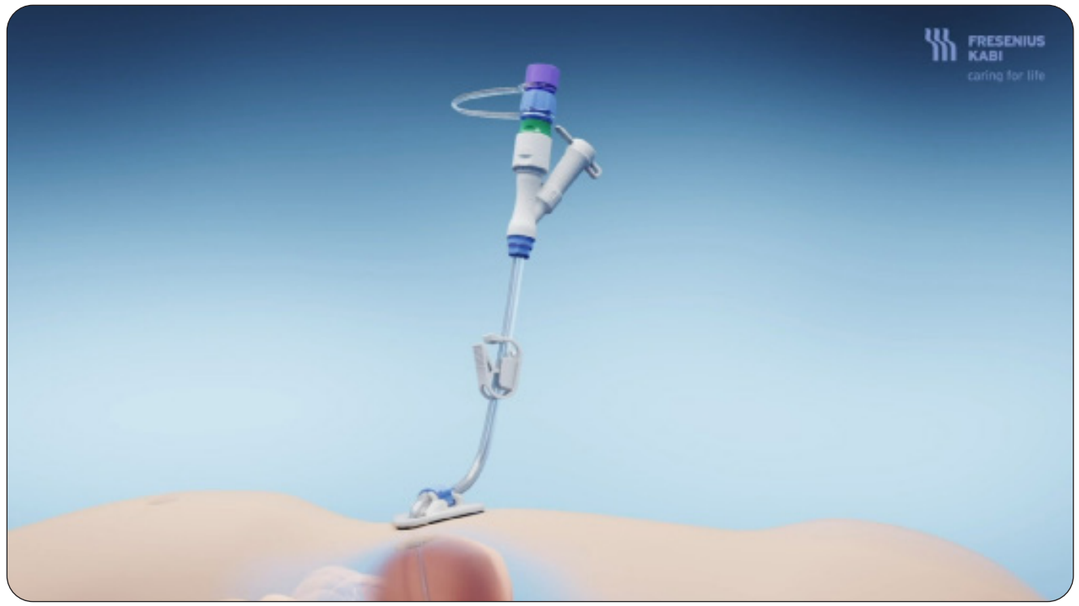

Screw the click connector into the ENFit connector as far as possible.




Open the tube clamp.



## Insertion of feeding tube into Freka PEG Pro endoscopically




Slide the Y-connector into the click adapter until you hear a soft click.

Close the caps on the ENFit intestinal access connector and the funnel/ENFit gastric connector.

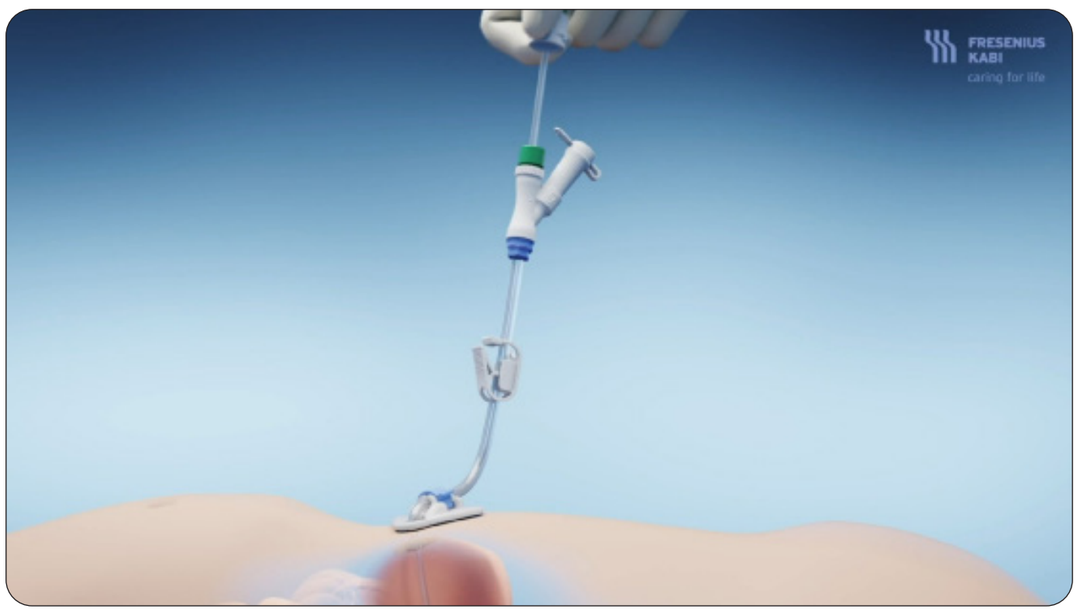
Careful aftercare and daily maintenance of the Freka intestinal tube and the Freka PEG Pro must be carried out according to the instructions for use.

**While it has been the objective of Fresenius Kabi to develop accurate, easy-to-follow insertion suggestions, each healthcare professional inserting the enteral product must evaluate the appropriateness of the following technique based on his or her medical training, experience and patient evaluation.**

# Surgical technique

## Removal of feeding tube from Freka PEG Pro

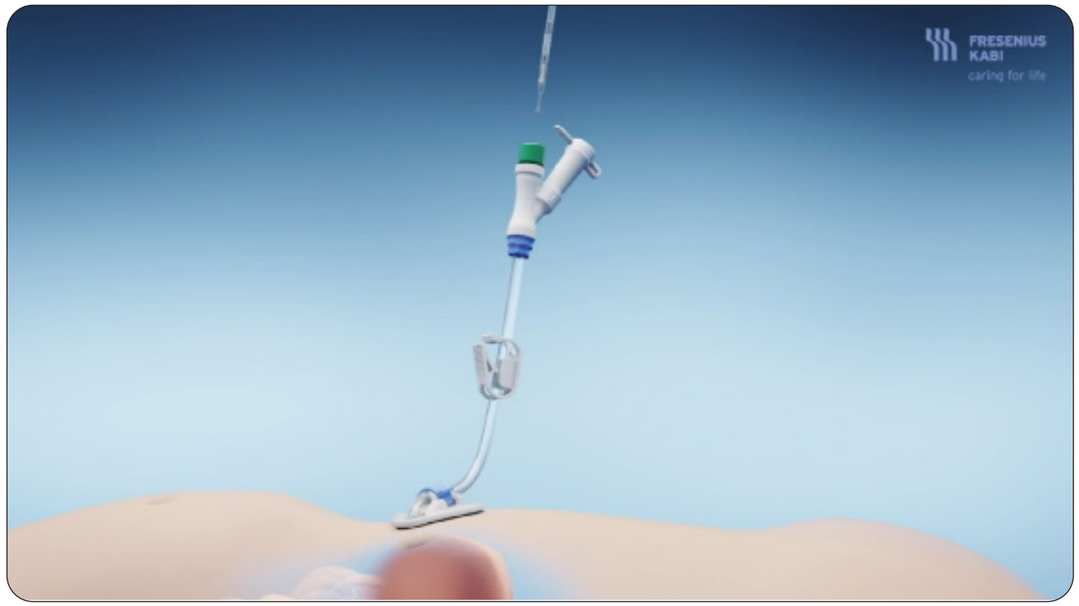

To remove or change the intestinal tube push the surfaces of the intestinal click adapter firmly together with two fingers.




Remove the click adapter and ENFit connector.



## Removal of feeding tube from Freka PEG Pro

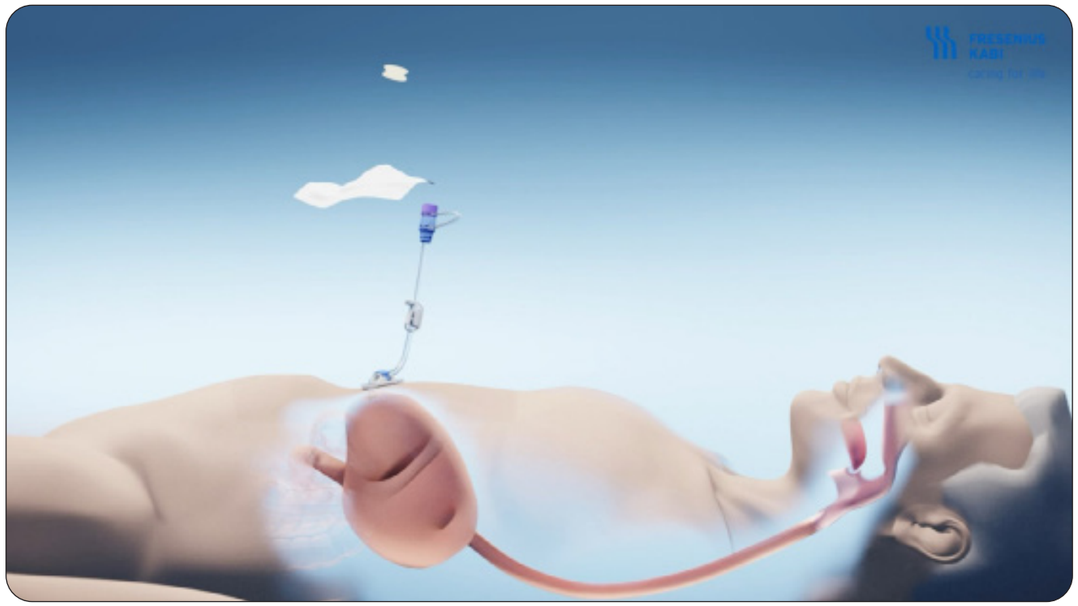



The intestinal feeding tube can then be carefully withdrawn and replaced with a new one if necessary.

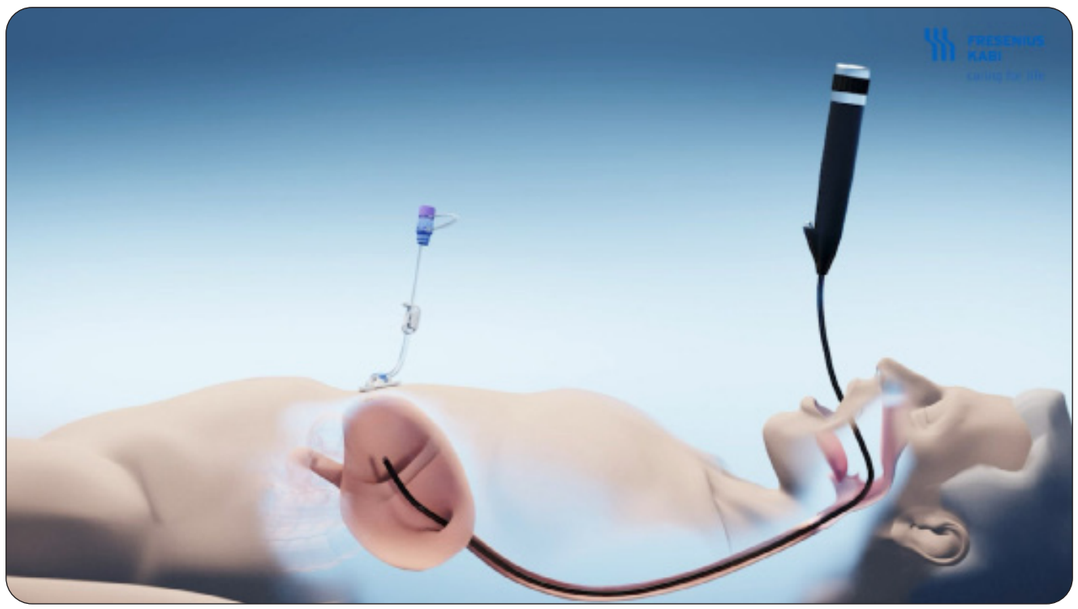
**While it has been the objective of Fresenius Kabi to develop accurate, easy-to-follow insertion suggestions, each healthcare professional inserting the enteral product must evaluate the appropriateness of the following technique based on his or her medical training, experience and patient evaluation.**

# Surgical technique

## Removal of Freka PEG Pro

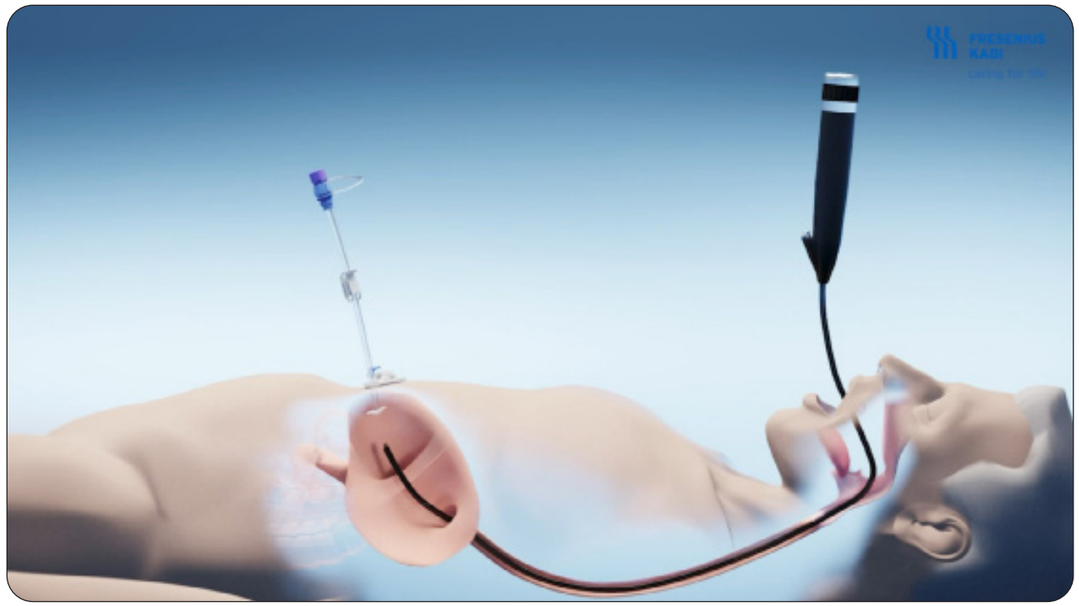


The Freka PEG Pro is removed endoscopically at least two weeks after placement to avoid peritonitis.  Remove any plasters from the Freka PEG.

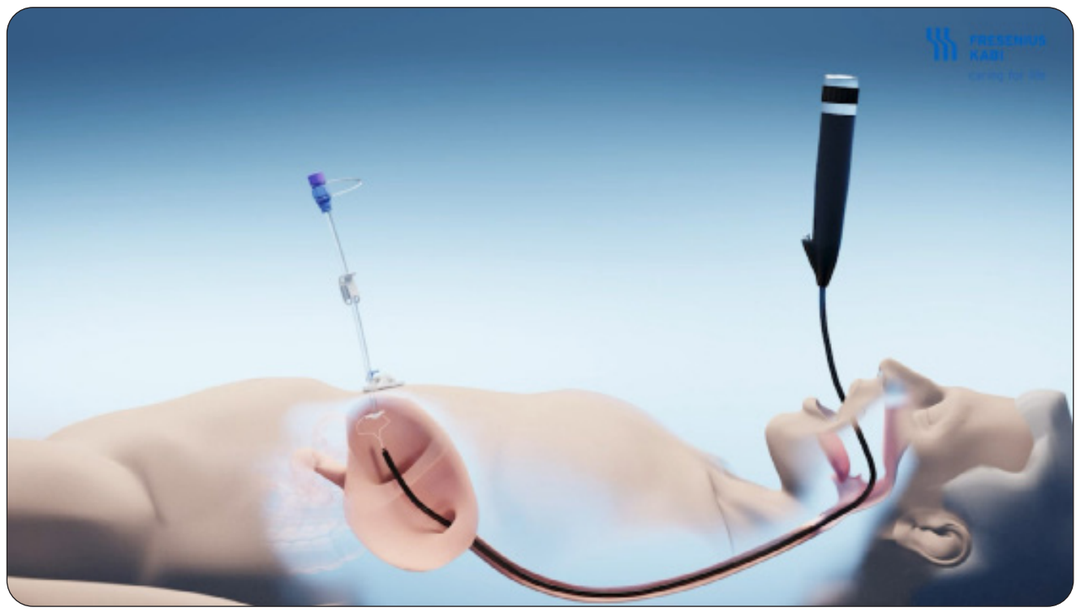


Insert an endoscope into the stomach and insufflate.

## Removal of Freka PEG Pro

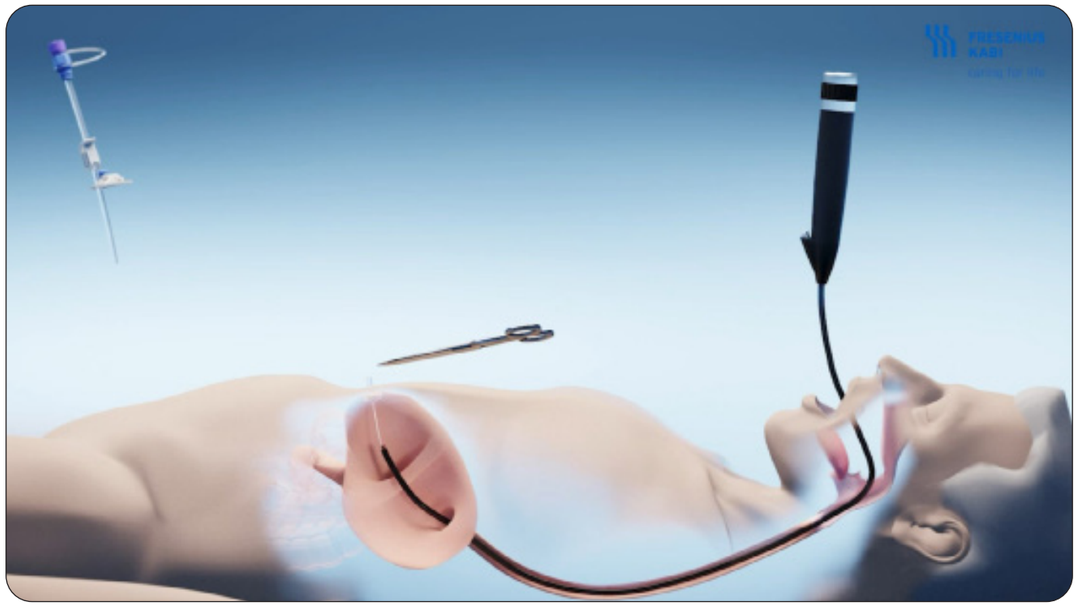


The outer retention plate of the tube is opened and the tube slightly pressed down into the stomach.



The inner retention plate is grasped with a polypectomy loop.

## Removal of Freka PEG Pro

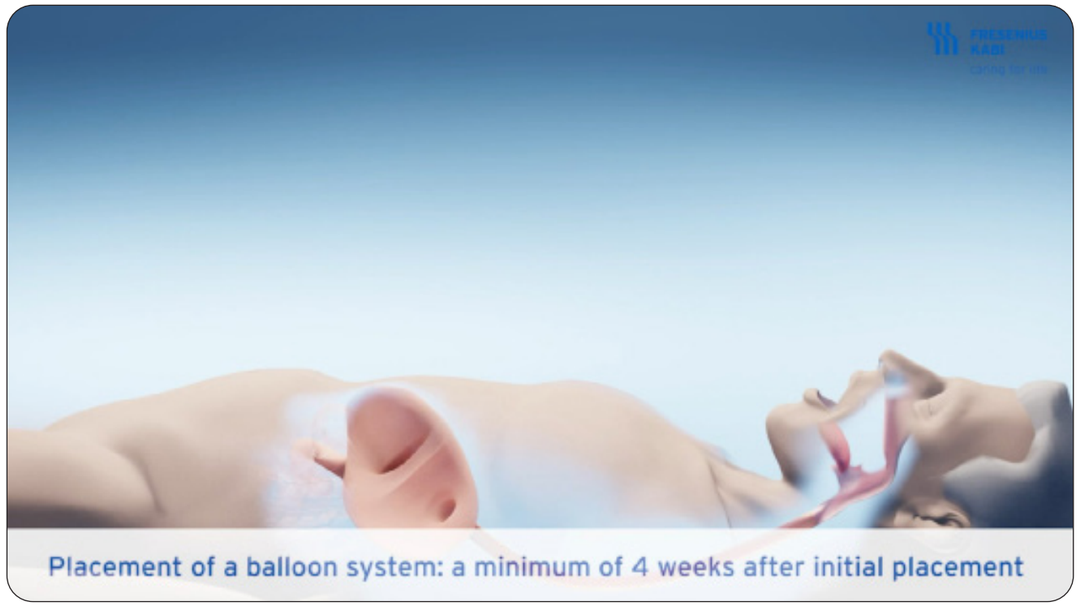


The inner retention plate is then tightened again by pulling gently externally and the external tube cut off.

Now the Freka PEG Pro tube can be pulled outwards with the endoscope.



## Removal of Freka PEG Pro




Once the stoma has headled after about four weeks a balloon system such as the Freka Belly Button or the Freka GastroTube can be applied in case further enteral feeding is required.

Once enteral nutrition is complete the stoma is covered with a plaster.

**While it has been the objective of Fresenius Kabi to develop accurate, easy-to-follow insertion suggestions, each healthcare professional inserting the enteral product must evaluate the appropriateness of the following technique based on his or her medical training, experience and patient evaluation.**

# **Instructions for use:** Freka PEG Pro 12 - 14 - 16 -20 FR

## Description

The Freka PEG is intended for percutaneous intragastric long-term feeding and gastric decompression or drainage by gravity for:

**Oncological disorders:**
stenosing tumours in the ear, nose and throat region or the upper gastrointestinal tract; PEG tubes may be used palliatively in inoperable cases or placed prior to surgery, radiotherapy or chemotherapy and removed when the patient has recovered and has a reliable and adequate oral intake.

**Neurological disorders:**
dysphagic states after cerebrovascular stroke or craniocerebral trauma, and in patients with cerebral tumours, bulbar paralysis, Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy.

**Other clinical conditions:**
AIDS Wasting Syndrome, short bowel syndrome, reconstructive facial surgery, prolonged coma, polytrauma, Crohn's disease, cystic fibrosis, chronic renal failure, congenital abnormalities, e.g. trachea-oesophageal fistula.

## 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:

- to avoid further loss of body weight
- to correct significant nutritional deficiencies
- to rehydrate the patient
- to promote the growth in children with growth retardation
- to improve the quality of life due to adequate nutritional intake.

Palliative gastric decompression or drainage by gravity:

- in the presence of a chronic gastrointestinal stenosis or ileus.

**Important information**
If the positioning of an exchange system (e.g. button) can be foreseen, a PEG 15 FR (REF: 775S643) should be used.

The PEG 15 FR as well as PEG 20 FR can be used for application of an intestinal tube as a guide tube.



# **Instructions for use:** Freka PEG Pro 12 - 14 - 16 -20 FR

Use of a wide-lumen gastric PEG (PEG 20 FR) is particularly recommended for:

- administration of high-viscosity tube feed nutrition
- decompression and drainage of viscous fluid
- frequent drug administration (also with specific galenics)
- use of the gastric port for instrument insertion for therapeutic/diagnostic purposes
- positioning of an intestinal tube for gastric decompression and intestinal feeding.

**Important information**
Positioning of a PEG is at the discretion of the healthcare professional in the case of the following indications. In certain circumstances, transnasal tube feeding may be recommended initially.

There is an increased risk of peritonitis in:

- severe cachexia
- multiple diseases and poor general condition
- clearly limited expectation of life
- long-standing diabetes.

There is a risk of fistula formation in:

- Crohn's disease.

## Contraindications

- 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 a terminal state
- severe erosive gastritis/ulcer
- tumour infiltration at puncture site.

## Warnings

1. If the positioning of an exchange system (e.g. button) can be foreseen, a PEG 15 FR (REF: 7755643) should be used.
2. Because of an increased risk of peritonitis the positioning of a PEG in the case of the following indications, on the basis of administrative discretion, is recommended:
   - severe cachexia
   - multiple diseases and poor general condition

- clearly limited life expectation or with long-standing diabetes.
- In certain circumstances, transnasal tube feeding may be recommended initially.

2. Lack of transillumination and positive needle aspiration test are an absolute contraindication for PEG insertion.
4. There is the possibility that the guide thread could snap when pulled with excessive force.
5. The tube should remain under moderate tension for 24 hours to promote good adaptation of the stomach wall to the abdominal wall. After that, the tube should be loosened. For further securing, leave approx. 5- 10 mm additional space. Do not pull the tube too hard on the outside, otherwise pressure necrosis can occur.
6. Clean and dry the puncture site, fixation plate and tube thoroughly, to ensure secure attachment. Let the puncture site dry properly. The tube should remain under moderate tension for 24 hours to promote good adaptation of the stomach wall to the abdominal wall.
7. If any difficulties are encountered during positioning check correct position of the tube endoscopically or by X-ray.
8. Ointments should only be used if strictly indicated and only for limited periods of time. Products which contain polyvidone/iodine complex should be avoided to prevent material damage of the tube.
9. In the case of healing disorders, and if food and secretion escape from the stoma, a healthcare professional must always perform an examination.
10. If the tube blocks, it needs to be changed. Under no circumstances should the lumen of the tube be cleared by force (small-volume ENFit syringe e.g. 2.5 or 5 mL) or by a guidewire. Otherwise there is a risk of perforating the tube.
11. Do not use fluids containing acids, particularly fruit teas or fruit juices, in conjunction with tube feed as they can cause coagulation which may clog the tube.
12. The tube must be carefully flushed with 20 mL of water before and after each administration of medication, preferably using a 20 mL ENFit syringe. Medication such as antacids must not be administered together with food under any circumstances.
13. Under no circumstances use an infusion pump designed for parenteral administration (risk of misconnection).
14. Remove PEG tube no sooner than 10 - 14 days after it has been positioned, otherwise there is a risk of peritonitis.
15. If the PEG can no longer be removed endoscopically, the use of other removal methods makes intensive follow-up checks essential.
16. This product is for single use only. Do not re-use. Reuse creates a potential risk of patient or user infection. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the structural integrity of the device.
17. Do not use the feeding tube if the expiry date is exceeded.



**Instructions for use:** Freka PEG Pro 12 - 14 - 16 -20 FR

### Warnings: PenBlade scalpel

1. The scalpel blade is sharp and can cause damage when used improperly.
2. If the button for extending the blade jams, do not use force to extend the blade.
3. Do not cover the tip of the PenBlade with your hand or other parts of the body when extending the blade.
4. Always retract the scalpel blade after use and when putting down the PenBlade.

### Precautions

1. Duration of use:
   In use to date, instances of the feeding tube being in place for several months without complications have been recorded if the following care instructions were observed.
   Frequent administration of large quantities of alcoholic drinks without immediate adequate rinsing of the tube may result in material defects to the tube, making a change necessary after only a short time in place.
2. Tube Care: Flush the tube with at least 20 mL of lukewarm water before and after each administration of nutrition - at least once a day preferably using a 20 mL ENFit syringe.

**Important information**

If the tube is blocked, it needs to be changed. Under no circumstances should the lumen of the tube be cleared by force (small-volume ENFit syringe e.g. 2.5 or 5 mL syringe) or using a guidewire. Otherwise there is a risk of perforating the tube.

Do not use fluids containing acids, particularly fruit teas or fruit juices, in conjunction with tube they can cause coagulation which may clog the feed.

3. Administration of Medication:
   Medication should preferably be administered via the tube in dissolved form. Preference should be given to liquid medication (in the form of drops or syrup).

**Important information**

The tube must be carefully flushed with 20 mL of water before and after each administration of medication, preferably using a 20 mL ENFit syringe. Medication such as antacids must not be administered together with food. If in doubt, consult the supervising physician or a pharmacist.

### Adverse events

1. There is a risk of fistula formation in Crohn's disease.
2. It is important for the tube to move freely in the stoma to prevent the inner retention plate becoming embedded ("buried bumper syndrome").

# **Instructions for use:** Freka PEG Pro 12 - 14 - 16 -20 FR

## Directions for insertion

### Preparation

- the patient should be fasted (at least 8 hours)
- oral hygiene maintained
- antibiotic prophylaxis (single dose) at the discretion of the physician
- insertion using aseptic surgical technique.

Percutaneous endoscopic gastrostomy (PEG) insertion is performed in a supine position and requires two operators. There should be a possibility for extraction by suction.

### Identification of appropriate puncture site

- After the endoscope has been passed into the stomach and the stomach sufficiently inflated with air, dim the lights and locate the appropriate puncture site by transillumination.
- The puncture site is palpated with the fingers from the outside, the gastric mucosa bulging outwards which is detectable by endoscope.

### Important information

Lack of transillumination and positive needle aspiration test are an absolute contraindication for PEG insertion.

**Gastropexy option.** See Gastropexy instructions for use if the optional gastropexy device is used.

### Puncture of the Stomach

### Important information

To protect against cuts, the trocar is locked in the basic position by a safety mechanism so that the cannula cannot be pushed forward. It is only unlocked by pressing the grey unlock button. If the unlock button is pressed in, the trocar is irreversibly unlocked and cannot be locked again.

Do not remove the trocar from the cannula until the puncture is complete. If the trocar is removed from the cannula, the needle guard automatically blocks the tip and puncture is no longer possible.

- Apply disinfection in a large area around the puncture site to make it sterile.
- Inject local anaesthetic to all layers of the abdominal wall, slowly advancing the syringe into the gastric lumen.
- Make a stab incision of approximately 3 mm (PEG 9 FR), 4 - 5 mm (PEG 15 FR) or 6 - 8 mm (PEG 20 FR) in width level with the puncture site. In any case it should be ensured that the incision at the puncture site is sufficiently large, to avoid e.g. wound infection.



# **Instructions for use:** Freka PEG Pro 12 - 14 - 16 -20 FR

- Advance the puncture cannula into the stomach under endoscopic control.
- Remove the puncture needle from the cannula.

### Insertion of the guide thread

- Advance the blue introducer device over the double thread until the loop protrudes approximately 1 mm from the opening.
- Attach the introducer device to the plastic cannula using the double thread and guide the thread into the stomach immediately.
- As soon as the thread is visible in the stomach, grab it with the biopsy forceps and withdraw the introducer device on the thread which automatically closes the safety air valve of the cannula.
- Withdraw the thread through the mouth with the endoscope.

### Securing the tube to the guide thread

- Fix the loop of the double thread at the fixation loop of the tube.

### Placement of the gastric guide tube

- Position the tube in the stomach by slowly pulling on the distal end of the thread.
- Pass thread and tube with the hand. Push the tongue of the patient to the side to prevent the tongue getting caught by the thread.
- A slight resistance will be felt when the tip of the tube enters the plastic cannula.
- Pull the tube together with the plastic cannula out through the abdominal wall until the retention plate abuts the inner gastric wall.
- Cut off the guide thread of the tube close to the cone.

### Securing the tube

- First pull the outer end of the tube through the hole of the fixation plate and then push the tube clamp onto the tube. Close the tube clamp.
- Pull on the tube until slight resistance is felt and keep it under tension.
- Clean and dry the puncture site, fixation plate and tube thoroughly, to ensure secure attachment.
- Apply a sterile slit compress on puncture site.
- Insert the tube into the fixation plate guide and secure in position using the clip. This ensures a secure, tight connection between the inner wall of the stomach and the abdominal wall.

### Important information

The tube should remain under moderate tension for 24 hours to promote good adaptation of the stomach wall to the abdominal wall. After that the tube should be loosened. For further securing, leave 5 - 10 mm additional space. Do not pull the tube too hard on the outside, otherwise pressure necrosis can occur.

**Attaching the outer adapter**

- Close the tube clamp. Then cut off the cone of the tube.
- Push the fixing screw for the ENFit connector over the tube.
- Push the pin of the ENFit connector as far onto the tube as possible and secure with the fixing screw.
- Pull off the screwing aid (outer white ring) in a downward direction and remove it.
- Check position of the tube endoscopically or by X-ray in case of difficulties during positioning.

**Aftercare of the puncture site**

- Loosen the clamp of the outer fixation plate and pull back the plate.
- Carefully clean the puncture site, the tube and the underside of the fixation plate. Volatile products (tinctures, sprays) should be preferred for this to minimise the period of contact with the tube.
- Let the puncture site dry properly.

**Important information**

Alcoholic solutions containing Phenoxyethanol or Isopropanol (such as Octenisept) should not be used, as they may damage the tube material of the feeding tube.

Ointments should only be used if strictly indicated and only for limited periods of time.

Products which contain polyvidone/iodine complex should be avoided where possible to prevent material damage to the tube.

- Push the tube carefully 3- 4 cm into the stoma and rotate every time the dressing is changed. It is important for the tube to move freely in the stoma to prevent the inner retention plate becoming embedded ("buried bumper syndrome").
- Pull on the tube gently until resistance is felt, place a sterile slit compress under the fixation plate, push the fixation plate back onto the slit compress and fix it with 5- 10 mm of additional space.

It is preferable to take adequate care of the puncture site by using special dressing kits, for example the "Hermann" Gastrostomy Dressing Kit. At the first wound healing phase, the dressing should be changed daily.  Further changes of the dressing will depend on the condition of the puncture site (approx. every 2 - 3 days).

The puncture site should be checked by a healthcare professional at least once a day in the first week after the feeding tube has been positioned.

Careful follow-up is required for patients with:

- cachexia





- multiple diseases
- poor general condition
- long-standing diabetes
- an increased risk of infection (e.g. local infection, peritonitis).

In the case of healing disorders, and if nutrition or secretion escapes from the stoma, a healthcare professional must always perform an examination.

**Notes on the feeding regimen**

For intragastric feeding, a fasting period after PEG placement of at least 1 - 2 hours is recommended.

The dosage of the nutrition should be increased gradually. Commercially available enteral feeding pumps should be used for pump-controlled continuous tube feeding.

**Important information**

Under no circumstances use an infusion pump designed for parenteral administration (risk of misconnection).

**Notes on tube removal**

Remove PEG feeding tube not sooner than 10 - 14 days after it has been positioned, otherwise there is a risk of peritonitis.

PEG feeding tubes are removed endoscopically as follows:

- insert the endoscope into the stomach
- advance the tube slightly in the direction of the stomach
- ideally, the inner retention plate should be grasped by a polypectomy snare
- lift the tube slightly and cut it on the level of the abdominal wall
- pull out the tube using the endoscope
- apply an adhesive dressing
- fasting is not necessary.

The PEG feeding tube can generally be removed without leaving a gastrocutaneous fistula.

It is recommended that the patient is kept under a healthcare professional's supervision until the stoma has closed completely.

**Important information**

If the PEG can no longer be removed endoscopically, the use of other removal methods makes intensive follow-up checks essential.

# **Instructions for use:** Freka intestinal tube 9 FR or 12 FR

## Description

The Freka Intestinal Tube 9 FR for Freka PEG 15 FR, or 12 FR for Freka PEG 20 FR, is intended for long-term intestinal feeding or long-term administration of medication.

## Indications

**a. Long-term intestinal feeding for example in:**

- prolonged coma
- gastric outflow obstruction
- neurological dysphagia with risk of aspiration
- post intestinal stenosis feeding.

**b. Gastric decompression/drainage by gravity and simultaneous intestinal feeding in:**

- impaired gastric emptying.

**c. Long-term administration of medication.**

## Contraindications

**Absolute contraindications**

- intestinal obstruction
- intestinal atony
- peritonitis
- sepsis.

**Relative contraindications**

- immune suppression
- radiation enteritis
- pancreatitis
- Crohn's disease (risk of a fistula formation)
- peritoneal carcinoma.

## Warnings

1. This is a single-use product. Do not reuse.
2. Please note the shelf life of the product.
3. Before the insertion of the Freka Intestinal Tube the Gastric Tube - Freka PEG must be positioned according to the directions for use. The Freka PEG Gastric serves as a guide tube for the Freka Intestinal Tube.
4. To facilitate intestinal tube insertion, the tip of the tube can be moistened with sterile water or Endo gel. Ensure that the metal pin of the ENFit Connector and the external end of the tube are free of grease, clean and dry. The use of lubricants is not required (increased risk of the intestinal tube becoming loose).



# **Instructions for use:** Freka intestinal tube 9 FR or 12 FR

5. A long-term intestinal tube should be inserted through the gastric lumen into the small intestine; it should be slack and straight-without loops. Loops remaining in the stomach, increases the risk of tube dislocation.
6. During placement do not release the attachment of the guidewire or push the guidewire forwards or backwards. The wire could inadvertently be pushed through the tube outlets. If the tube becomes blocked, it needs to be changed.
7. To prevent the Freka Click Adapter being opened inadvertently, the screwed connection cannot be undone without destroying the adapter. If the screwed connection is undone, a new Freka Click Adapter of the correct size must be used.
8. Under no circumstances should the lumen of the tube be flushed forcibly (small-volume ENFit syringe, e.g. 2.5 or 5 mL) or unblocked by using a guidewire. There is the risk to disconnect the intestinal tube or tube perforation.
9. Do not use acid containing fluids, as they may cause it to coagulate.
10. The tube must be flushed with 20 mL water before and after each administration of medication preferably using a 20 – 60 mL ENFit syringe. Drugs, especially antacids, must not be mixed with feed under any circumstances.
11. Parenteral infusion pumps must not be used to administer enteral nutrition.

## Precautions

**Duration of Use**

Based on clinical experience, the tube can remain in place for many months without complications.

Frequent administration of alcohol can result in material defects in the tube, requiring it to be changed after only a short time in situ.

The tube has to be flushed with water after each administration. Material defects caused by medicines do not generally occur if the tube is flushed before and after each administration of medication.

**Notes on Aftercare**

The gastric PEG tube should be carefully moved backwards and forwards in the stoma once a day when the puncture site has healed. The tube should not be turned under any circumstances to prevent the formation of loops and dislocation of the intestinal tube.

Free movement of the tube in the stoma is important to avoid an embedding of the inner retention plate ("buried bumper syndrome").

Flush the feeding tube with 20 mL of lukewarm water before and after each administration of nutrition or at least once a day using a 20 - 60mL ENFit syringe. In the case of double lumen use, the limb of the tube not being used for feeding should be flushed once a day in the same way. If the tube becomes blocked, it needs to be changed.

# **Instructions for use:** Freka intestinal tube 9 FR or 12 FR

Under no circumstances should the lumen of the tube be flushed forcibly (small volume ENFit syringe e.g. 2.5 or 5 mL) or unblocked using a guidewire. There is the risk of intestinal tube disconnection or tube perforation.

If the intestinal tube becomes blocked, it must be replaced.

**Notes on the administration of medicines**
Where possible, medicines should be administered in dissolved or liquid form to the T-piece or needlefree connector on the giving set. Liquid medicines (drops or syrup) are preferred.

The tube must be flushed with 20 mL water before and after each administration of medication preferably using a 20 - 60 mL ENFit syringe.

Drugs, especially antacids, must not be mixed with feed under any circumstances. If there is any doubt, consultation of the doctor or a pharmacist is recommended.

## Adverse effects

Free movement of the tube in the stoma is important to avoid an embedding of the inner retention plate ("buried bumper syndrome").

## Directions

**Insertion of the Intestinal Tube**
Before insertion of the Freka Intestinal Tube the gastric tube Freka PEG must be positioned according to  the directions for use. The Freka PEG serves as a guide tube for the intestinal tube.

**Fixation the ENFit Connector to the Gastric (Guide) Tube**

- Close the tube clamp.
- Cut off the ENFit Connector of the gastric tube.
- Push the blue and white fixation screw for the ENFit connector over the gastric tube.
- Push the pin of the Y-Connector as far as possible onto the tube and secure with the fixation screw. Pull off the screwing aid (outer white ring) in a downward direction and remove it.

**Positioning the Intestinal Tube**

- Open the blue fixation screw on the intestinal tube 3 - 4 turns and push the guidewire before the metal insert at the distal end of the tube to stretch the pigtail bend.
- Fix the guidewire in position again using the fixation screw.
- Open the tube clamp on the gastric tube.
- Insert the intestinal tube carefully through the intestinal access of the Y-Connector (“i” for intestinal - green).
- To ensure a lasting placement, for insertion of the intestinal tube via the gastric lumen into the small intestine, the tube should be slack and straight without loops. Any loops remaining in the stomach increases the risk of dislocation.



# **Instructions for use:** Freka intestinal tube 9 FR or 12 FR

- In the case of endoscopic placement, it is recommended to grasp the distal end of the tube using the following endoscopic instruments and push the tube under visual control until it has passed beyond the ligament of Treitz:
  - the foreign body forceps, 2:1 teeth
  - the two-arm gripper
  - or the three-arm polyp gripper.
- The tube can also be pushed using an image sensor control with the aid of the guidewire.
- Once the required position is reached, remove the guidewire.
- When withdrawing the endoscope, the tube should be kept in position by using the forceps or the gripper.

**Important information**
During placement do not release the fixing of the guidewire or push the guidewire forwards or backwards. The guidewire could inadvertently be pushed through the tube outlets.

**Fixation of the Intestinal Tube to the Gastric (Guide) Tube**

- To securely position the intestinal tube, close the tube clamp.
- Cut off the intestinal tube approximately 3 - 4 cm above its exit from the gastric guide tube.
- Push the green/white ENFit Click Adapter from the white end into the intestinal tube.
- Push the metal pin of the ENFit connector as far as possible into the intestinal tube and screw the ENFit Click Adapter tightly until the stop is reached.
- Open the tube clamp.
- Push the connected intestinal ENFit Click Adapter over the ENFit intestinal access of the Y-Connector until an audible click is heard.
- To facilitate the intestinal tube insertion, the tip of the tube can be moistened with sterile water or Endogel.
- Ensure that the metal pin of the ENFit Connector and the external end of the tube are clean and dry. If MCT oil is used, there is an increased risk that the intestinal tube may come off.

**Using the Y-Connector for double-lumen use of the tube**
When used for gastric decompression and intestinal feeding the gastric access of the Y-Connector (“g” for gastric - white) is used for decompression and feed is administered via the intestinal access of the Y-Connector (“I” for intestinal - green) preferably using an enteral feeding pump.

**Notes on the feeding regimen**
If the gastric PEG has been in situ for 1 - 2 hours or if food is administered to the small intestine, the administration of nutrition can start If the gastric PEG is simultaneously inserted with the intestinal tube and if feed is being administered intragastrically, It is recommended that a fasting period of approximately 1 - 2 hours is adhered to.

# **Instructions for use:** Freka intestinal tube 9 FR or 12 FR

Feed should be administered slowly in the beginning and increased gradually. A standard enteral feeding pump should be used for continuous feed administration.

Parenteral infusion pumps must not be used to administer enteral nutrition.

**Notes on removal and changing of intestinal tube**
To remove/change the intestinal tube, squeeze the contoured surfaces of the intestinal Click Adapter firmly between two fingers and pull off. After that carefully pull out the intestinal tube and replace it with a new one if required.

To prevent the Freka Click Adapter ENFit being opened inadvertently, the screwed connection cannot be undone without destroying the adapter.

If the screwed connection is undone, a new Click Adapter of appropriate size must be used.



# **Instructions for use:** Gastropexy device

## Checking the function of the gastropexy device

Carefully remove the gastropexy device from its packaging, and inspect the following components for possible damage or defect.

- Protective cover for the puncture needle
  - carefully remove the protective cover.
- Suture-holding loop wire
  - the loop should be formed at the tip of the needle by pushing the blue insertion rod.
- Push the release button to withdraw the loop into the device. Check that the thread feed roller rotates smoothly. The loop must remain in the needle.
- Insert the suture material into the opening of the suture inlet until a slight resistance is felt. Rotate the suture feed roller to further advance the suture material. Advance the suture material to the needle tip, but keep the suture material in the needle.

## Selecting a suitable puncture site

- Introduce the endoscope and adequately insufflate the stomach. Dim the light and secure a suitable puncture site by transillumination.
- Press the illuminated area with your finger. The bulging of the gastric mucosa should be clearly recognisable through the endoscope.
- The puncture site should be clearly marked externally on the abdomen.
- Two/three fixation sutures provide adequate fixation of the gastric wall to the abdominal wall. Decide on a case-by-case basis whether more fixation sutures are required. The fixation sutures should be 3 cm apart.

**Important information**
A positive needle aspiration test in the absence of transillumination is an absolute contraindication for placement of a percutaneous feeding tube.

## Performing the gastropexy

- Wash the intended puncture site and a large area around it to make it sterile.
- Apply anaesthetic to all layers of the abdominal wall that are going to be punctured.
- Advance the tip of the anaesthesia needle into the stomach slowly. Hold the needle in a vertical position under endoscopic monitoring.
- Ensure that the suture and the loop remain within the gastropexy device.
- Position the sliding plate between the first and second marking (1 - 2 cm away from the tip) in direction of the needle tips.
- Make sure that both needles remain parallel during puncture, otherwise the needles could be bent or damaged.
- Place the gastropexy device at the marked puncture site and puncture with both needles in a vertical position.

## **Instructions for use:** Gastropexy device

- Use endoscopy to check that both needles have sufficiently punctured the stomach (approx. 15 – 20 mm).
- After checking the position of the needles, push the blue loop insertion rod to form the suture-holding loop wire. The suture holding loop wire must be located directly beneath the needle opening for the suture inlet.
- Rotate the suture feed roller to advance the suture material through the suture-holding loop wire. Insert the suture material sufficiently far, though at least up to 30 mm. The suture material should be clearly visible when using the endoscope.
- Press the release button to fix the suture material.
- Carefully withdraw the Gastropexy Device until both needles are outside of the stomach. Make sure the hand does not cover the yellow suture feed roller and that the suture material runs freely.
- Before withdrawing the Gastropexy Device, make sure that the blue insertion rod returns to the original position completely.
- Give additional support to the blue insertion rod by pulling the insertion rod slightly in an upright position to keep an appropriate retention force.
- The loop wire must not protrude from the needle tip. If the loop wire protrudes from the needle tip even slightly, it bends, breaks or doesn't form properly after the needles are punctured.
- In the case the blue insertion rod cannot be returned into its original position and the loop remains protruded from the needle tip, push the blue insertion rod downwards again and pull it gently up with the thumb. Repeat this several times. After that, the loop wire can be withdrawn into the needle.
- While withdrawing the Gastropexy Device, make sure that the suture material run freely . Do not cover the yellow suture feed roller with your hand.
- Do not withdraw the Gastropexy Device with force as this may result in damage of the suture material or the loop wire.

## Notes

# Ordering information

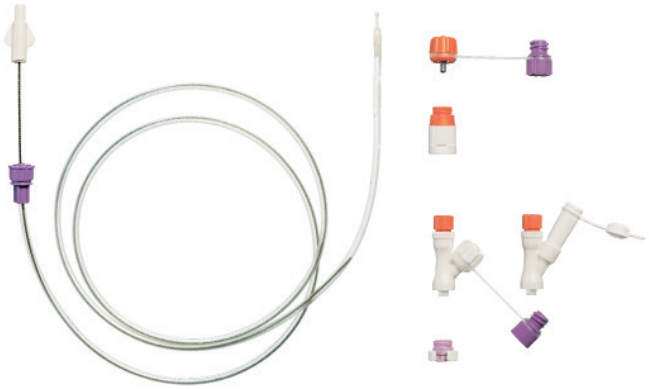
### Freka PEG Pro Gastric with Insertion Kit

Single lumen gastric tube.

**Article codes:**

| | |
|---|---|
| M90800346 | PEG Pro 12 FR |
| M90800347 | PEG Pro 14 FR |
| M90800349 | PEG Pro 16 FR |
| M90800348 | PEG Pro 20 FR |

**Sales Unit:** 15x 1



### Freka Intestinal Tube with Insertion Kit

Double lumen intestinal feeding tube.

**Article codes:**

| | |
|---|---|
| M90800373 | 9 FR for PEG Pro 16 FR |
| M90800350 | 12 FR for PEG Pro 20 FR |

**Sales Unit:** 5 x 1

### Freka PEG Pro Repair Kit

For repair of an in situ Freka PEG Pro.
- Tube clamp
- Freka ENFit connector
- Fastening screw
- Fixation plate

**Article Codes:**

| | |
|---|---|
| M90800400 | PEG Pro 12 FR |
| M90800401 | PEG Pro 14 FR |
| M90800402 | PEG Pro 16 FR |
| M90800403 | PEG Pro 20 FR |

**Sales Unit:** 1 x 1

### Gastropexy kit

Gastropexy allows attachment of the gastric wall to the abdominal wall with sutures using a unique device available from Fresenius Kabi.
- Gastropexy device
- 2 x sutures
- Cotton balls

**Article Code:**
7601363

**Sales Unit:** 8 x 1


FRESENIUS KABI

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai, NSW 2080 Australia
Ph: 1300 732 001
PM2024..1954, Pub. May 2024
Fresenius Kabi New Zealand Limited
The HSBC Tower
Level 14, 188 Quay Street
Auckland 1010, New Zealand
Ph: 0800 144 892
TAPS MR10538