FRESENIUS KABI

Freka® Pexact II

Direct Puncture Gastrostomy with secure and reliable Gastropexy

Product Code: 7601365

With **Gastropexy device** option

Product features and surgical techniques for healthcare professionals

Insertion through direct puncture gastrostomy.

15
FR

freka.com.au

Product features

Latex **free** | Luer **free** | PVC **free** | DEHP **free**

Freka Pexact II ENFit

For patients who require long term intragastric feeding and/or gastric decompression. The gastropexy technique can be used primarily or where a PEG cannot be placed using a pull technique such as in patients with head and neck cancer.

Biocompatible

Tube and fixation plate made of biocompatible silicone.

Tube clamp

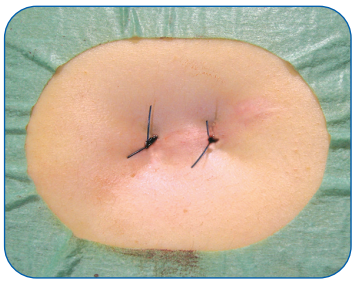
Used to open and close the PEG tube. Clamp has side wall protection to minimise false clamping.

Innovative design

- Proven balloon retention system.
- Can be removed without need for endoscopy.
- Replaceable with either a Freka GastroTube or Freka Belly Button.

Gastropexy option

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



Combines the benefits of two procedures

The technique combines the advantages of a conventional PEG placement with the benefits of a secure apposition of the 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 85%[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. Thus, a better blood circulation around the stoma enhances stoma healing and early tube mobilization reduces the incidence of 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

Suitability for specific patients

A consecutive series[1] of 31 amyotrophic lateral sclerosis patients in whom endoscopic gastrostomy was considered too dangerous to perform underwent CT-guided percutaneous gastropexy and gastrostomy. All procedures were performed with a 15 FR Freka Pexact gastrostomy kit.

The procedure was performed successfully in 30 of 31 patients (one case without prior gastropexy) with a median age of 60 years.

No serious adverse events such as peritonitis, persistent local bleeding, systemic blood loss, or any local infection requiring surgical intervention were observed. Follow-up resulted in 7,473 cumulative gastrostomy days from the date of first placement.

These results suggest that the gastropexy technique is feasible and secure and may be especially advantageous in cases where endoscopic gastrostomy and sedation are contraindicated.

Patients with head and neck cancers may require nutritional support during and after treatment of their cancers and this is commonly done via a gastrostomy. Endoscopic gastrostomy placement is usually performed using a pull-through technique. However, pulling the PEG bumper past the tumour may risk seeding malignancy to the PEG site. In these cases a direct puncture technique may be preferred.

319 Freka Pexact insertions[2] were identified in 317 patients with an average age of 58 years. 99% (n=316) patients had a head and neck cancer as the indication. Insertion via direct puncture technique was successful in 99% (n=316) and unsuccessful in 3 (0.9%) patients.

It was concluded that Freka Pexact is a secure and reliable method of gastrostomy tube placement and overall, the complication rate fell using the Freka Pexact and the gastropexy technique.

In another study, 89 patient procedures[3] were performed under conscious sedation. Freka Pexact PEG placement was achieved in all cases. Minor haemorrhage from the puncture site in one patient was the only immediate operative complication. Complete tube displacement during the first 30 days occurred in 7 patients (7.9%). 5 of these had a new gastrostomy tube placed at the bed-side without difficulty. No significant PEG-site infections were recorded. The overall 30 day complication rate was 12.3%.

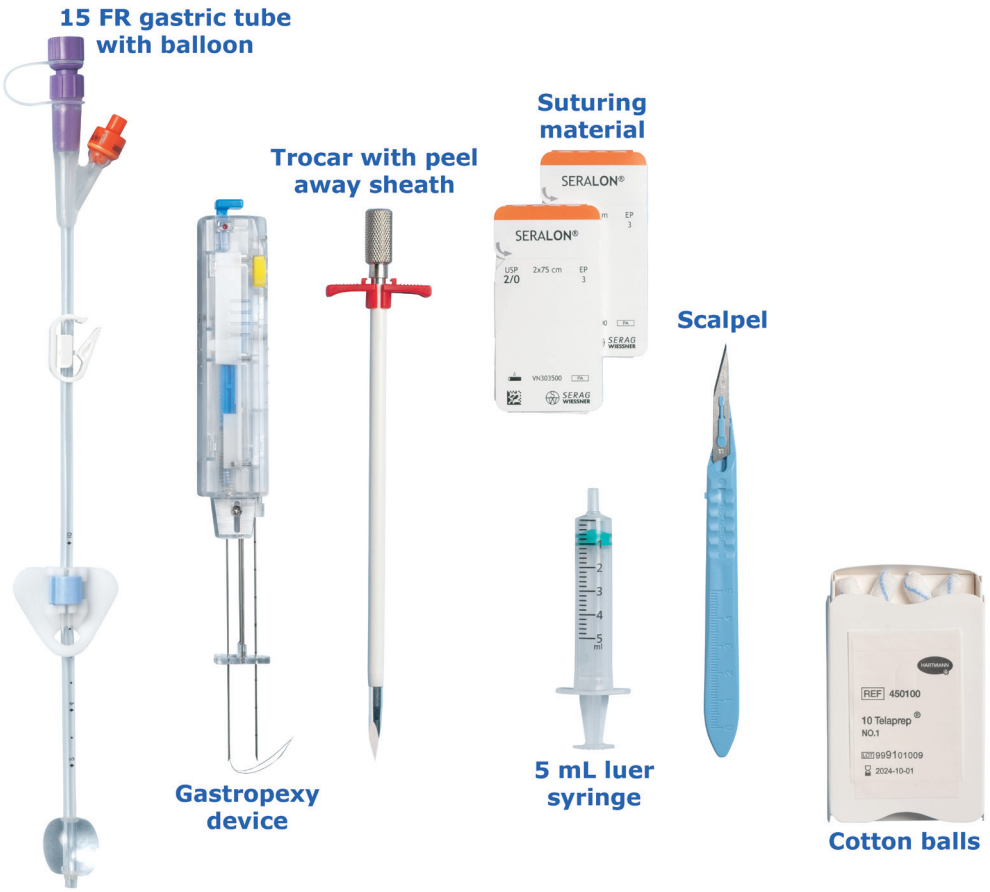
Serious complications were rare, but tube displacement remains a significant problem. Minor complication rates were comparable to the standard pull through technique, although PEG site infection appeared less often. In conclusion, Freka Pexact using the gastropexy technique provided a reliable direct puncture method for PEG placement.

1. Maximilian de Bucourt, Federico Collettini, Christian E Althoff, Florian Streitparth, Johannes Greupner, Bernd Hamm and UK Teichgraber. CT fluoroscopy-guided percutaneous gastrostomy with loop gastropexy and peel-away sheath trocar technique in 31 amyotrophic lateral sclerosis patients. Acta Radiologica 2012; 53: 285-291. DOI: 10.1258/ar.2011.110662.

2. Suhail Ahmed, Katherine Bowering, Naveen Polavarapu, Roger Nicholson, Paul Thomas, Richard Sturgess. Pexact: Analysis of 319 Procedures Performed at the Digestive Diseases Unit, University Hospital Aintree. Gastroenterology, Volume 138, Issue 5, Supplement 1S-1-S-906, 2010 DDW Abstract Supplement.

3. H. Gupta, R. Manikandan, A. Byrne, R. Nicholson, P.A. O'Toole. Pexact Direct-Puncture PEG Placement: Our First 12 Months Experience. Volume 65, No. 5 : 2007 Gastrointestinal Endoscopy AB279.

Kit contents: Freka Pexact II



Freka 15 FR PEG tube

23 cm +/- 1 cm silicone PEG tube with distal balloon. 5.0 mm outside diameter.

Gastropexy device

Allows attachment of the gastric wall to the abdominal wall with sutures.

Trocar with peel away sheath

17.5cm pyramidal 16 FR trocar with peel away plastic sheath.

Suturing material

Non-absorbable suture material for use in the Gastopexy device.

Scalpel

Sterile scalpel for incising.

5 mL luer slip syringe

5 mL luer slip syringe for balloon testing and inflation.

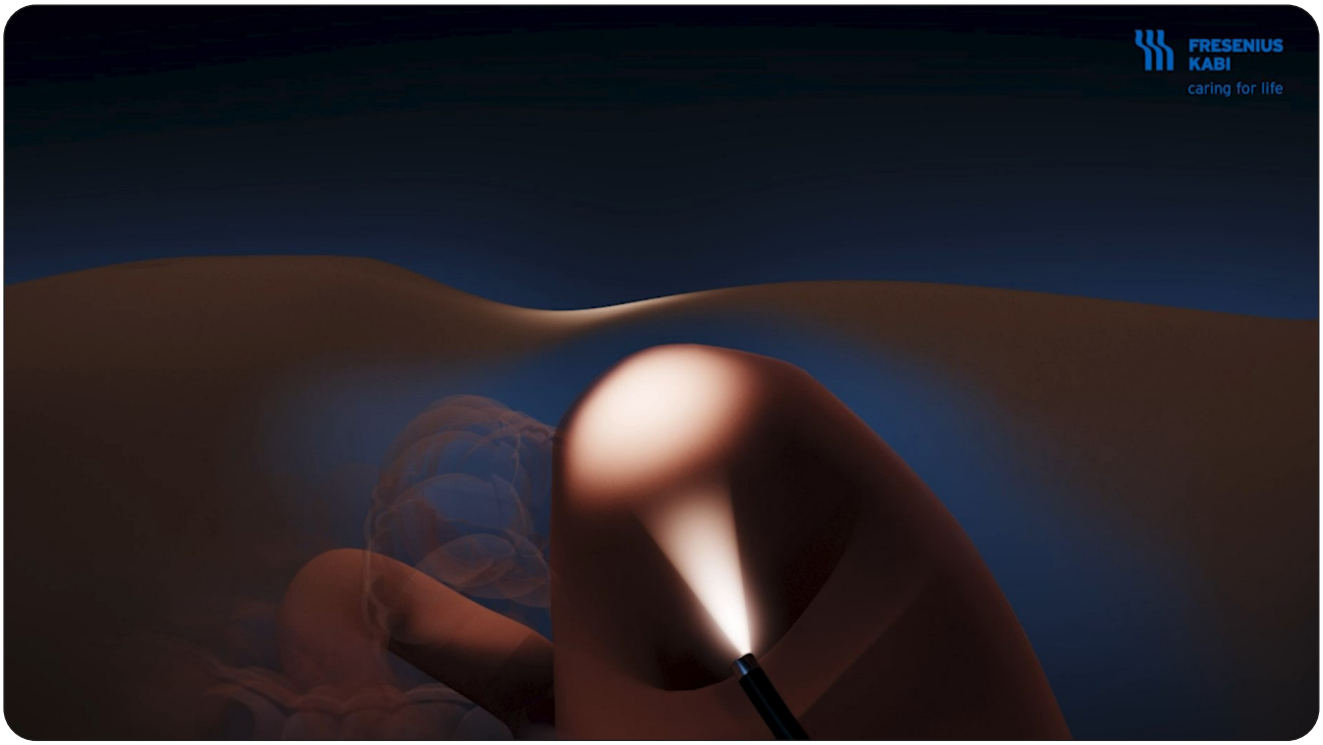
Cotton balls

To absorb secretions and buffer the gastropexy threads in case of initial swelling.

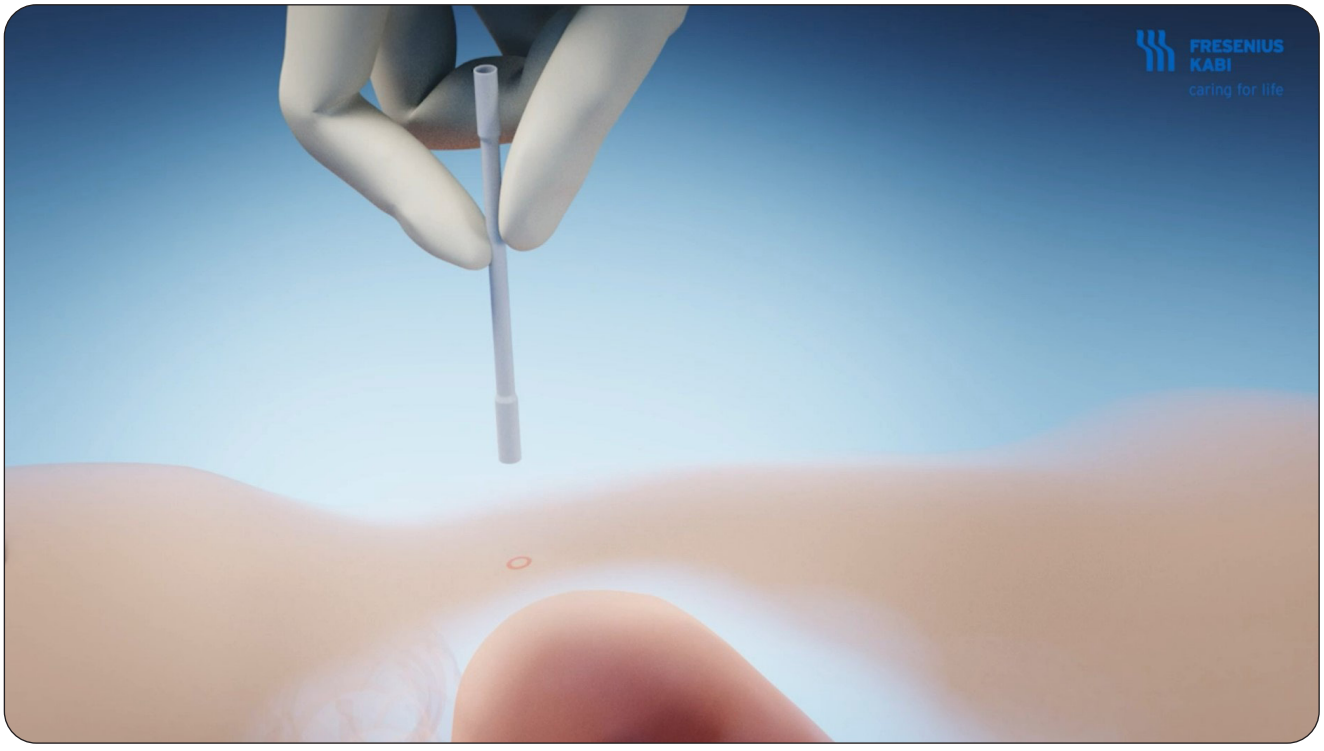
Surgical technique

Percutaneous direct puncture method

Note: alternative technique for when endoscopic pull through method is contraindicated.



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.

Testing the Freka Pexact balloon before use

Inflate the balloon with 5 mL of sterile water by inserting the luer slip syringe into the orange balloon valve and check visually for leaks.

Knead the balloon gently between the fingers. Then aspirate all the fluid back out of the balloon.

Testing the gastropexy 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.

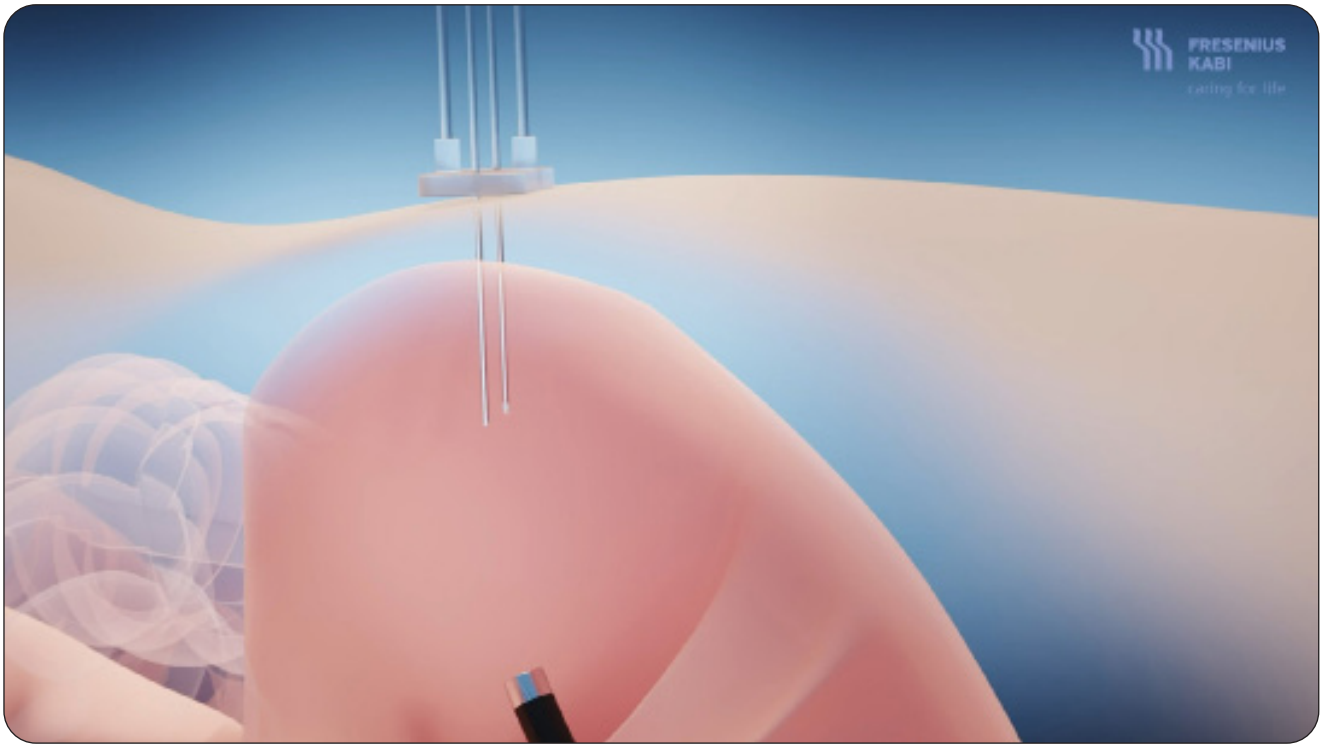
Testing the gastropexy device before use

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 it if required using the yellow thread feed roller.

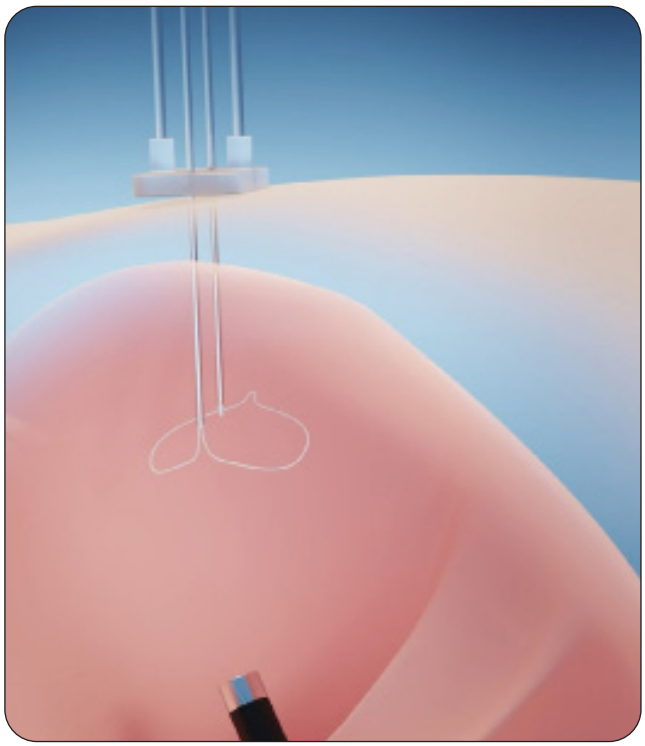
Percutaneous direct puncture method

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

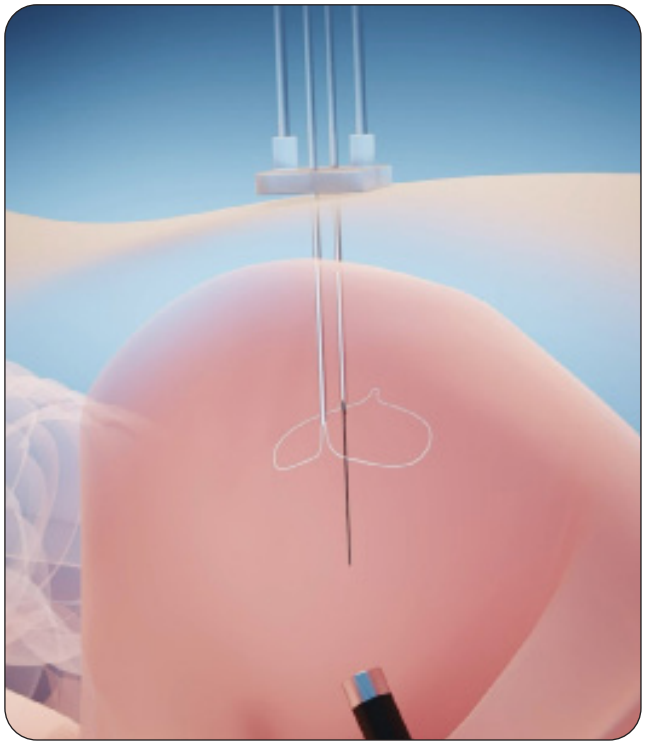


Carefully puncture the stomach with the gastropexy device at the marked site. The two needles must remain parallel to each other during insertion.

Percutaneous direct puncture method

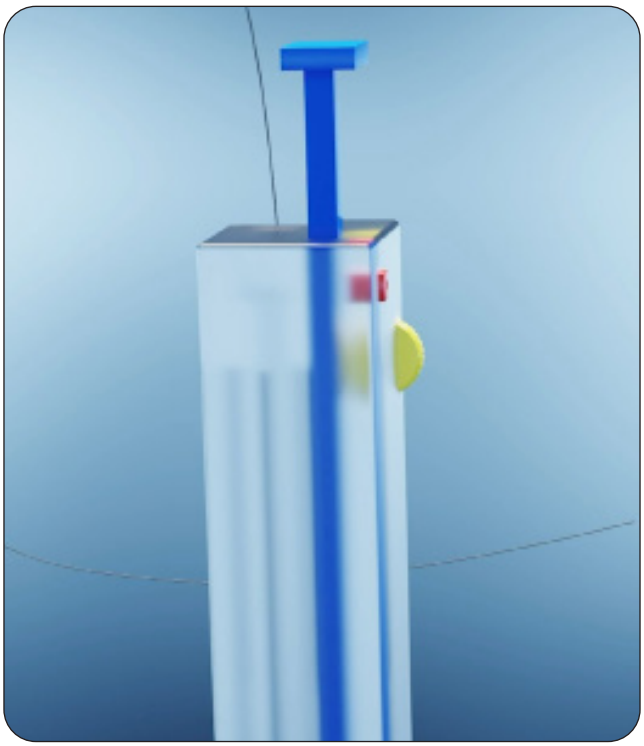


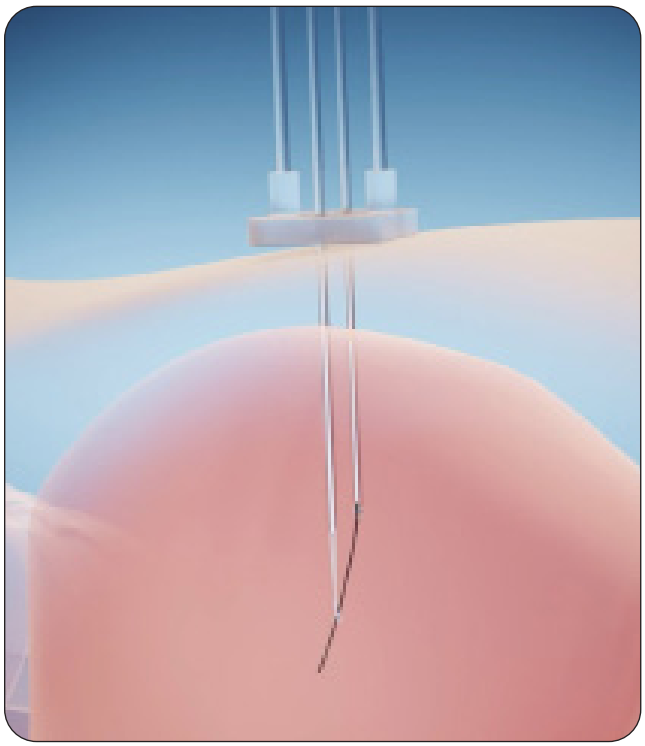
When approximately 15-20 mm of both needles are endoscopically visable the blue trigger is pressed so that the loop forms directly under the opposite needle.



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 direct puncture method

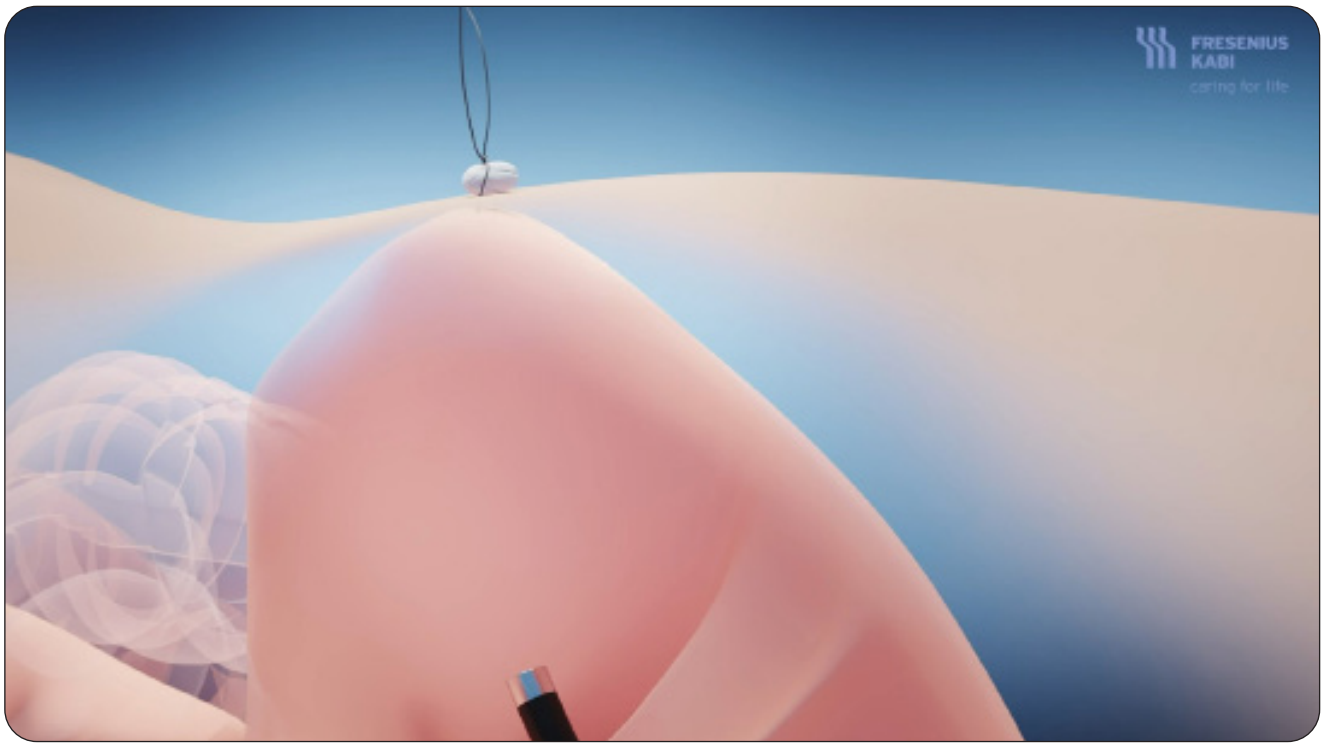




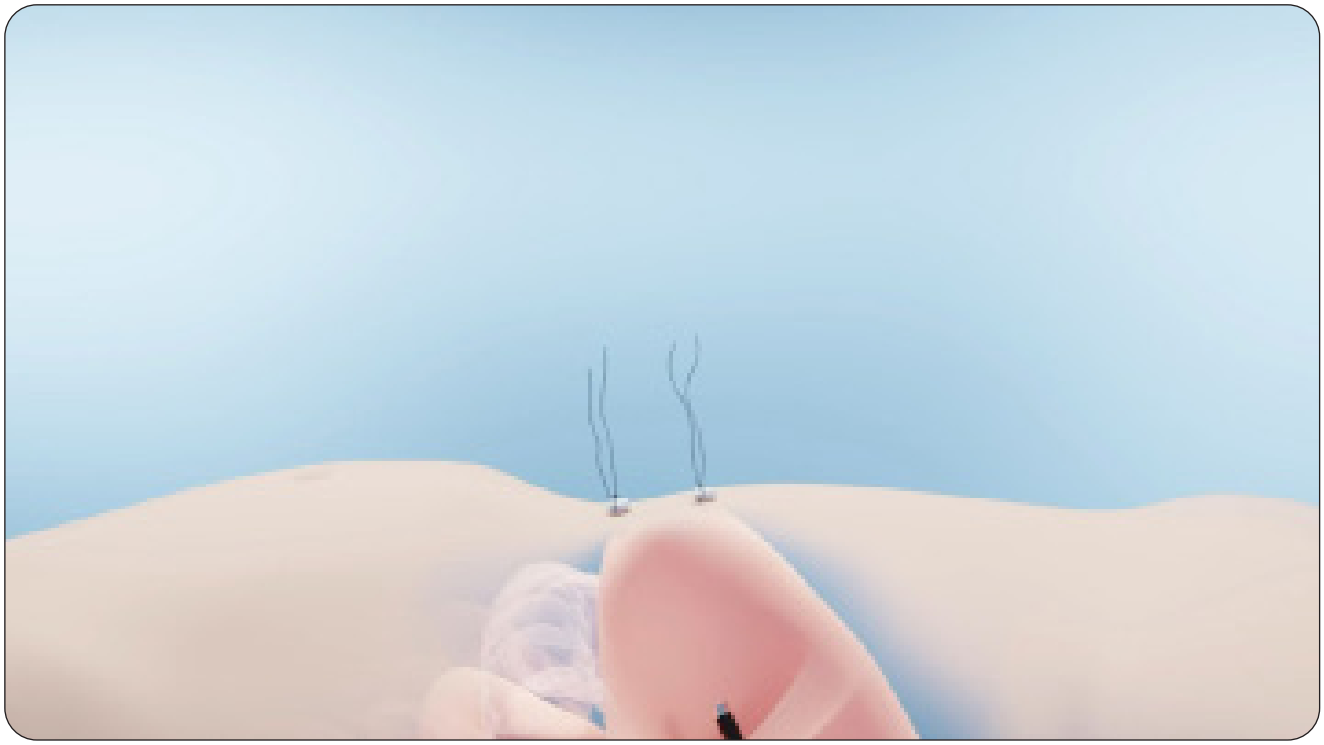
Press the red release button. This attaches the suture material with the loop to the tip of the needle. The loop must no longer protrude from the needle.

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

Percutaneous direct puncture method

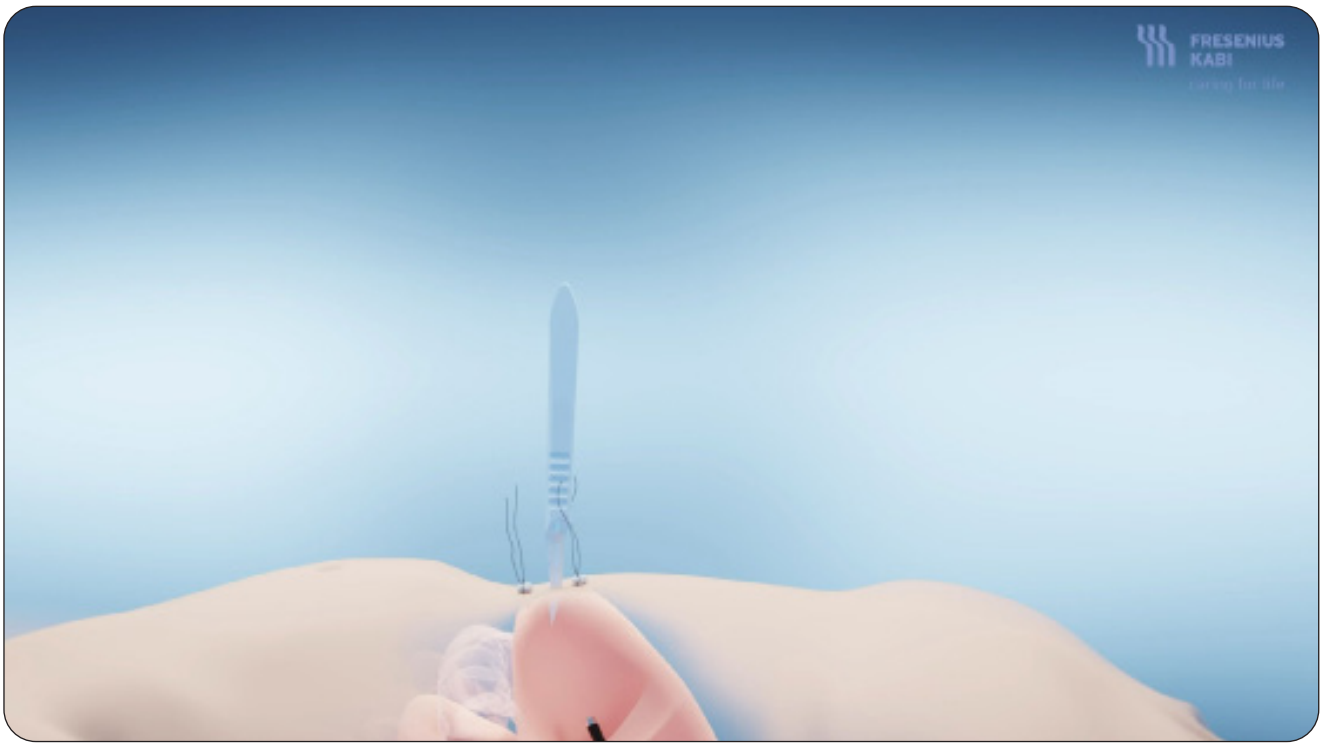


Place a cotton ball between the threads and tie them tightly into a knot. Do not cut off the ends of the threads. Cotton balls absorb secretions and buffer the threads in case of initial swelling.



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

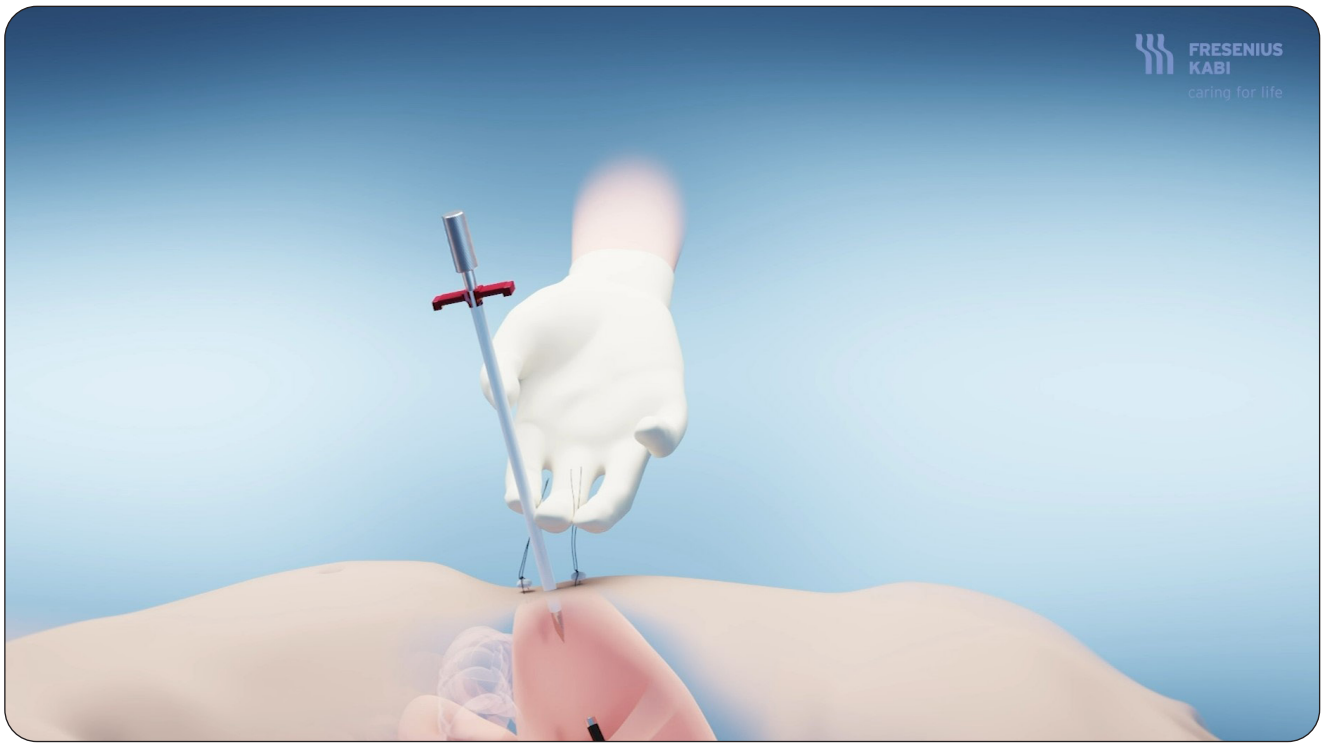
Percutaneous direct puncture method



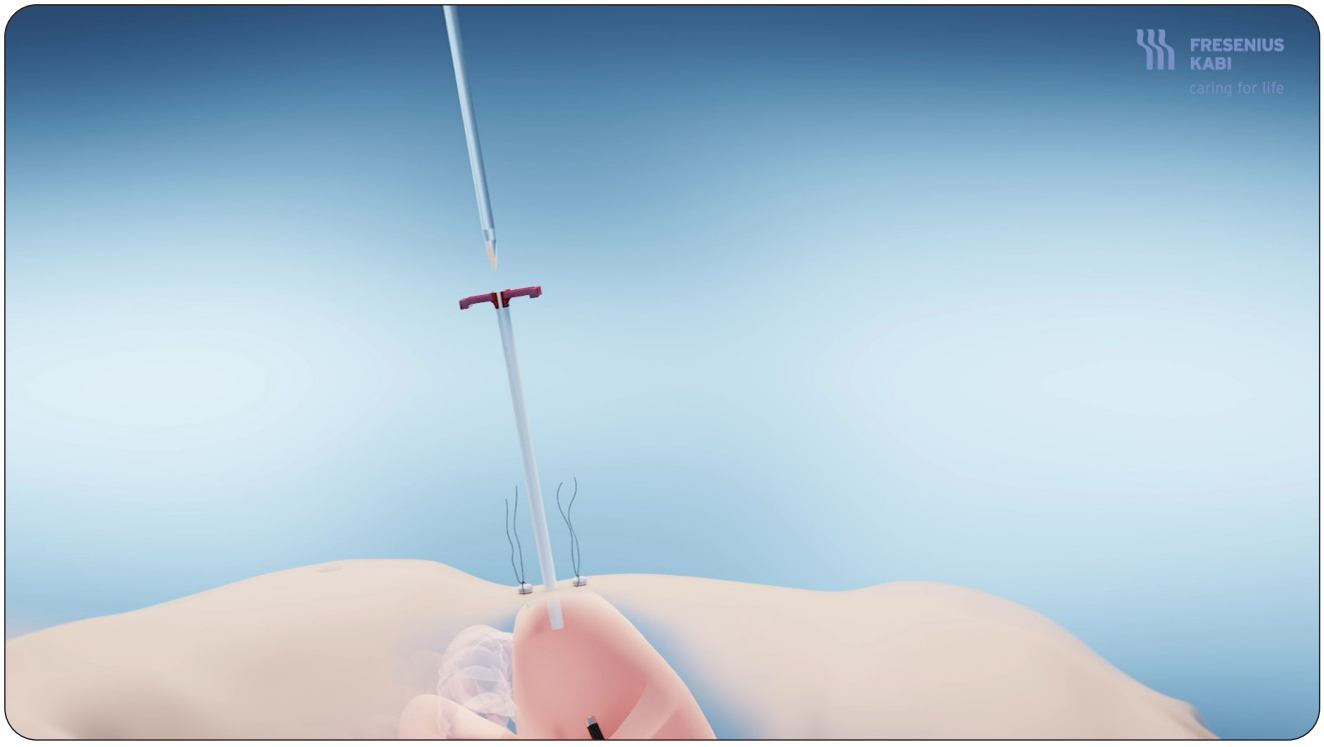
The puncture site is located between the gastropexy sutures and a suitable stab incision made with the scalpel.

Pull on the sutures until the abdominal wall is lifted.

Percutaneous direct puncture method

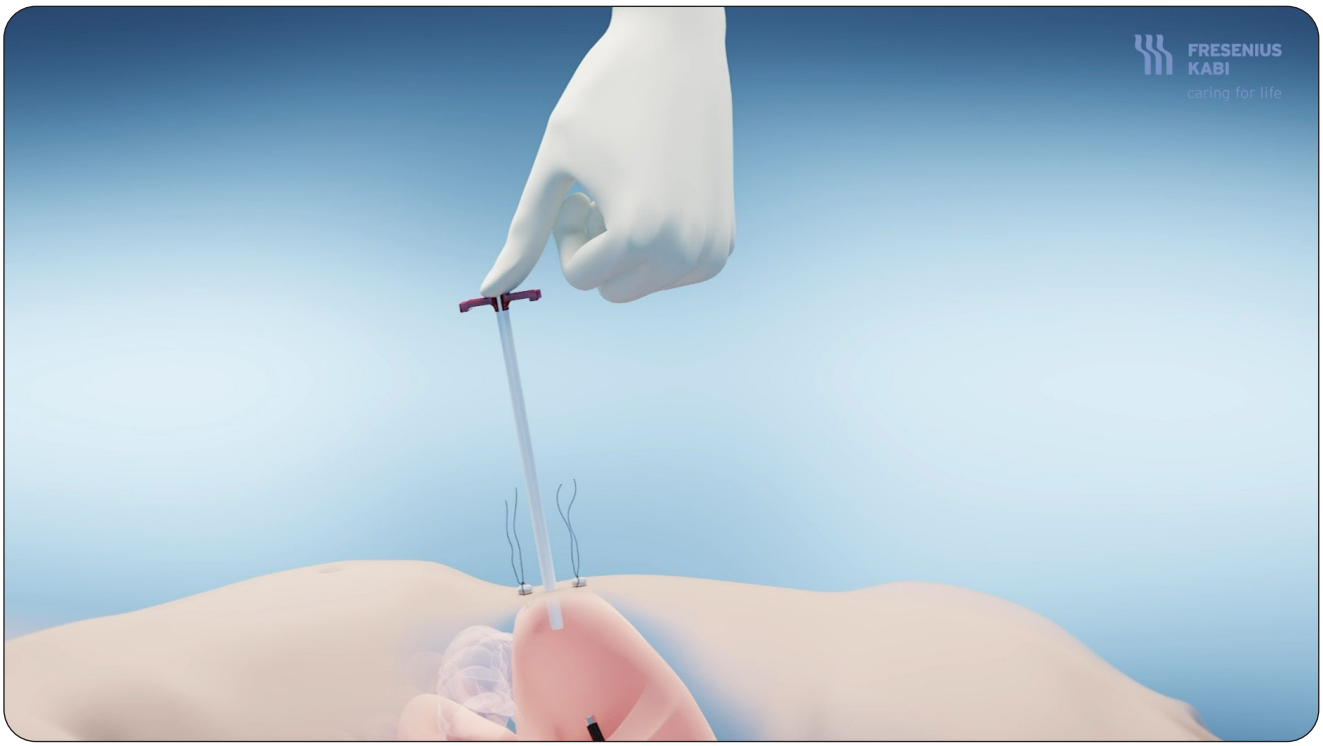


The trocar is inserted vertically into the stomach with constant light pressure.

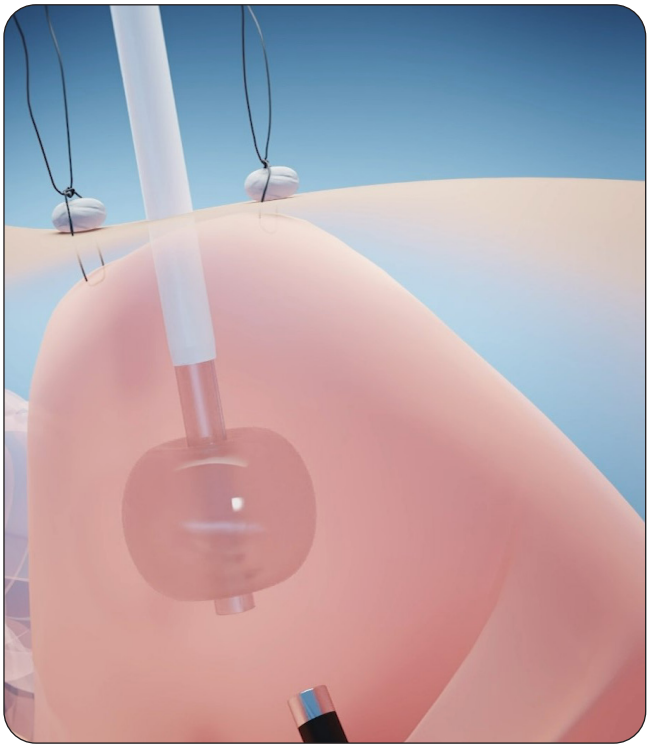


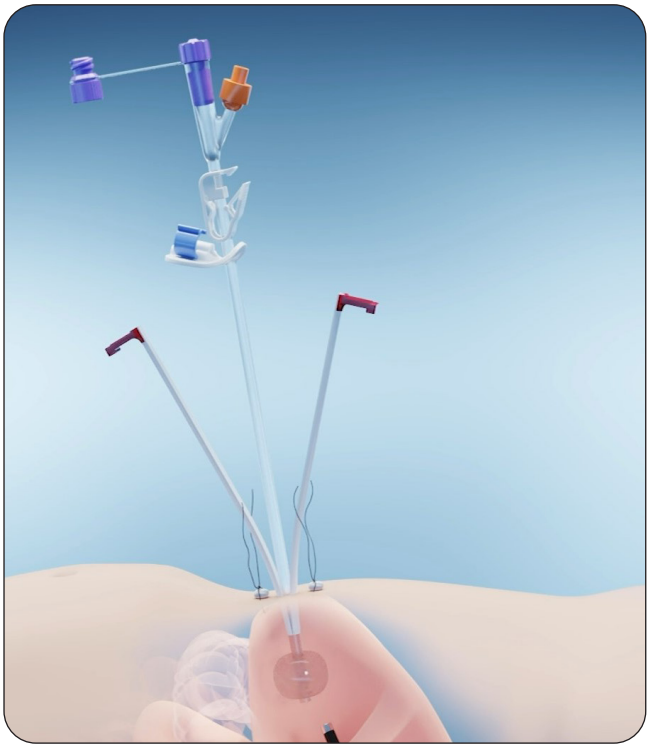
The trocar is removed from the peel away sheath.

Percutaneous direct puncture method



Close the sheath with a finger to avoid the air in the insufflated stomach from escaping.

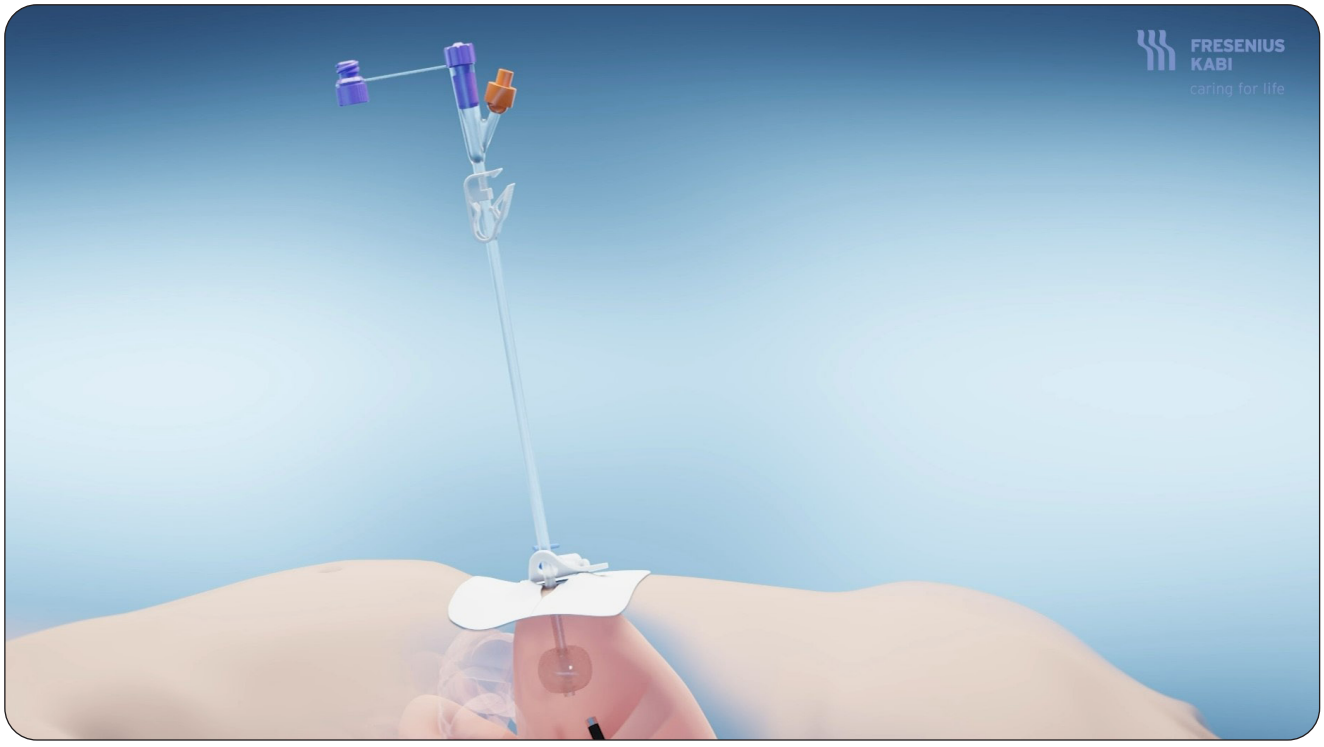




The Freka Pexact II is now inserted though the sheath into the stomach and the balloon inflated using 5 mL of sterile water. The sheath is pulled apart carefully and removed.

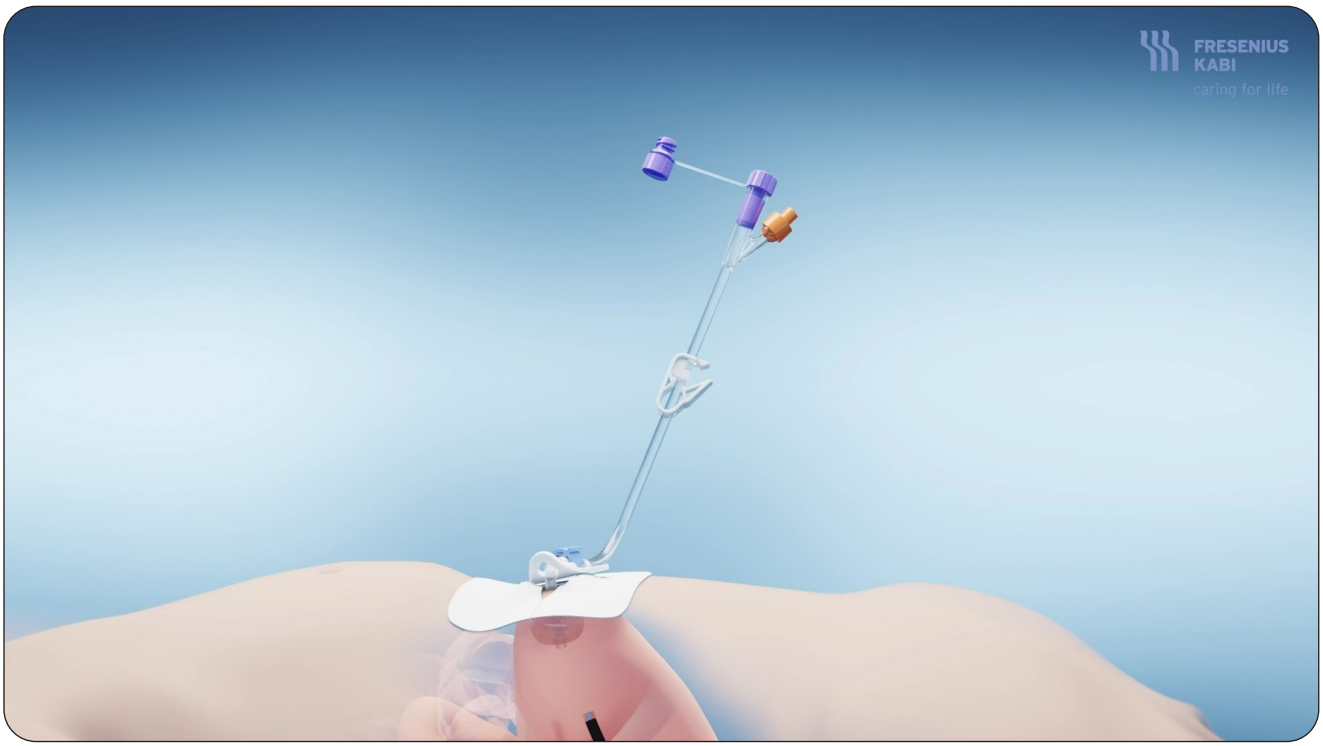
Percutaneous direct puncture method

The gastropexy sutures can now be cut off and the puncture site cleaned.

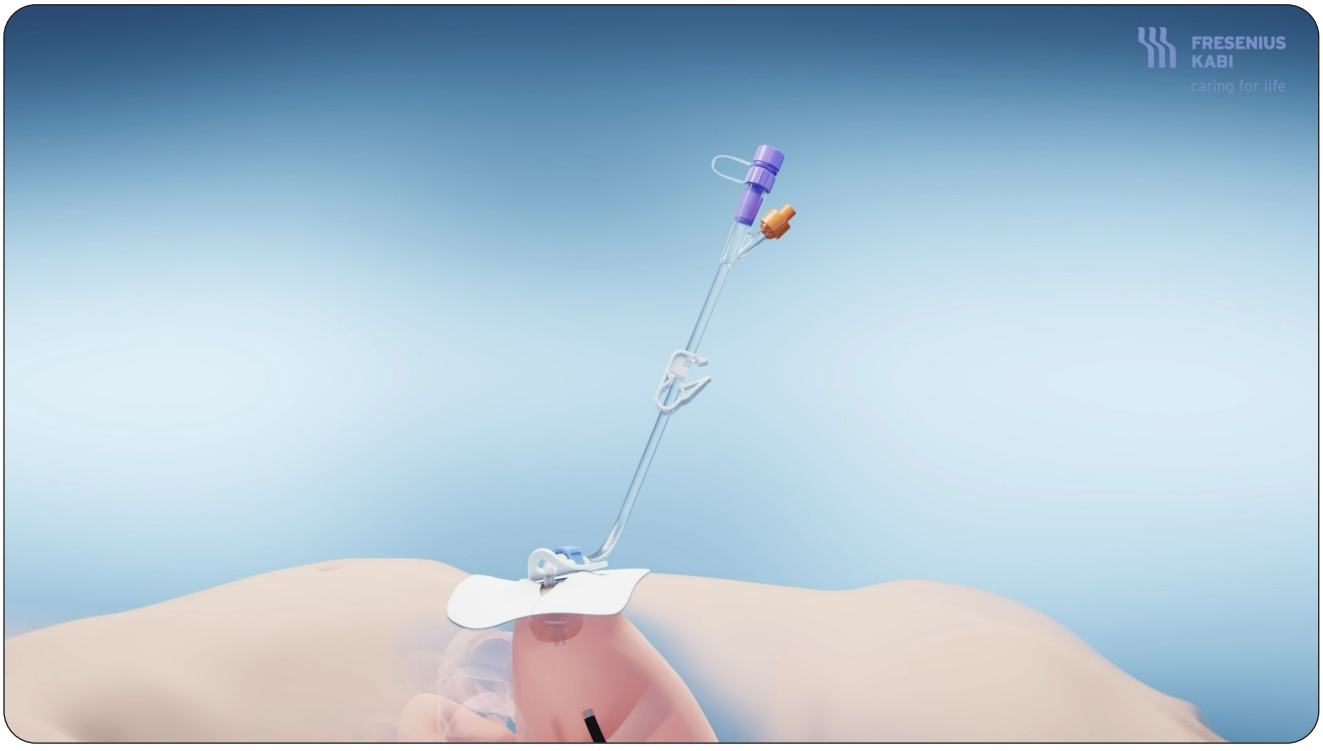


Apply a sterile split dressing and advance the retention plate down to where the tube enters the stoma site.

Percutaneous direct puncture method

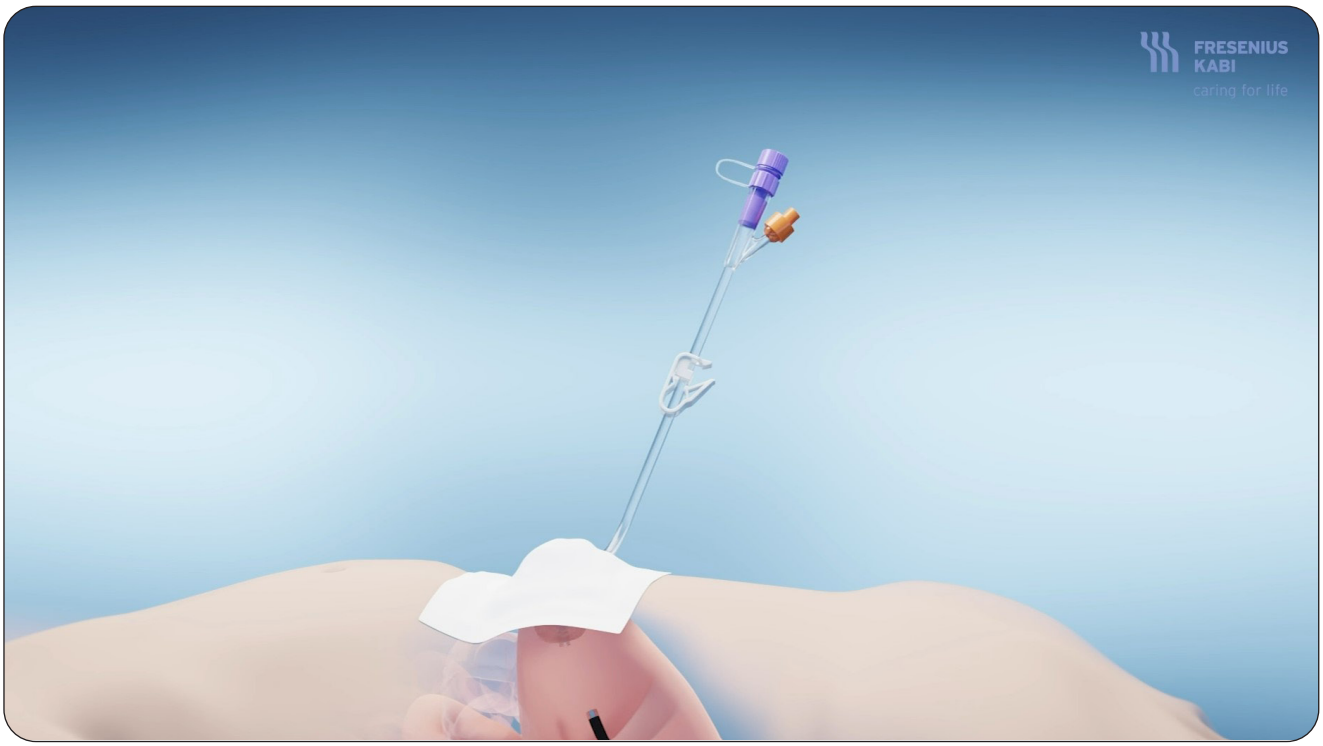


Tighten the tube and close the clamp on the outer retention plate.



Close the cap of the tube but leave the tube clamp open.

Percutaneous direct puncture method



Cover the exit point of the Freka Pexact II tube with sterile dressings.

Dressing kits are available from Fresenius Kabi for this purpose.

The gastropexy sutures remain in place until the stoma site is fully healed.

Careful aftercare and daily maintenance of the Freka Pexact II 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.

Instructions for use: Freka Pexact II, 15 FR

Indications

Long term intragastric feeding and/or gastric decompression, especially for patients where a PEG cannot be placed by pull technique such as:

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

Contraindications

Absolute contraindications

- no transillumination and positive needle aspiration test
- blood clotting disorders
- severe general wound-healing disorders
- sepsis
- peritonitis
- acute pancreatitis
- obstructions in the lower gastrointestinal tract
- tumor infiltration at the puncture site
- ulceration at puncture site
- visible liver tumor.

Relative contraindications (to be decided case-by-case)

- immunosuppression
- ascites
- peritoneal carcinosis
- peritoneal dialysis (PD)
- ventriculoperitoneal shunt
- severe psychoses
- anorexia nervosa.

Preparation

Prior to placement the following is recommended to avoid bacterial infections:

- fasting (approximately 8 hrs) before tube placement
- antibiotic prophylaxis (single-dose)
- insertion using aseptic surgical technique

The procedure is performed with the patient in supine position and under endoscopic monitoring.

Instructions for use: Freka Pexact II, 15 FR

Placement method

Checking the balloon function

- Inflate the balloon with 5 mL of sterile water by inserting the luer slip syringe into the orange balloon valve
- Gently knead the balloon and check for leaks.
- Deflate the balloon completely to enable a proper sliding through the peel-away sheath.

Selecting a suitable puncture site

- Insert the endoscope into the stomach and adequately insufflate with air.
- Dim the light and establish a suitable puncture site by transillumination.
- Palpate the illuminated area with a finger, the bulging of the gastric mucosa should be clearly seen via the endoscope.
- Mark the puncture site on the abdomen.

Important information

- Positive needle aspiration test without transillumination is an absolute contraindication.

Gastropexy. *See Gastropexy instructions for use.*

- A fixation of the gastric wall to the abdominal wall can be achieved with 2 fixations. It should be decided case-by case if 3 or more fixation sutures are necessary. Keep 3 cm distance between the fixations.

Puncturing with the Trocar

- After the Gastropexy has been completed, the area between the Gastropexy sutures provides the intended puncture site.
- Make a 4-5 mm wide stab incision.
- Remove the protective sleeve from the trocar.
- Place the trocar in a vertical position at the intended puncture site and advance it carefully into the stomach under constant gentle pressure.

Important information

When inserting the trocar, pull up the Gastropexy sutures strongly. This helps to avoid damaging the opposite stomach wall.

Insertion of balloon tube

- Remove the trocar from the peel away sheath. Press a finger on the sheath to avoid pressure loss in the stomach.
- Pull the external fixation plate of the balloon tube proximally to ensure that the balloon tube can be pushed as far as possible into the sheath.
- Insert the balloon tube through the sheath far enough into the stomach. Observe by endoscopic control that the tube tip lies freely in the stomach.

Instructions for use: Freka Pexact II, 15 FR

Important information

Before filling the balloon, check the correct position of the balloon endoscopically or by x-ray. The balloon could be damaged if the balloon is inflated inside the sheath or at the tip of the sheath.

- Fill the balloon with 5 mL sterile water via the orange balloon filling valve. Do not use air!
- Make sure that the luer slip syringe is inserted sufficiently far to open the valve properly for inflating or deflating the balloon.
- Bend the handles of the peel-away-sheath to the left and right to split the sheath. Pull the sheath very gently and remove it from the stoma. Keep the balloon tube in the stomach.

Important information

- Inflate the balloon with sterile water slowly.
- Do not use air to inflate the balloon.
- Never inflate the balloon with more than 5 mL sterile water.
- For inflating and deflating the balloon use a luer slip syringe only. Other products may damage the valve.

Initial care of the puncture site

- Clean and dry the puncture site and apply a split compress. Keep the feeding tube under slight tension.
- Position the fixation plate at the stoma. Insert the tube into the plate guide and secure it with the clip.
- Cover the retention plate with a dressing and plaster to avoid manipulation and tension.
- Check the balloon by gently pulling it against the stomach wall.

Important information

- Check the correct position by endoscopically or by x-ray.
- The balloon tube should be under slight tension to avoid pressure necroses.
- Do not suture the external retention plate to the skin, as this makes mobilisation and checking impossible.
- For disposal of the trocar, cover it carefully again with the protection cap. Take care not to injure yourself.

Care instructions for the puncture site

- Change dressing and check the puncture site daily during the first week.
- After that, the frequency of dressing changes will depend on the prevailing wound conditions. (approximately every 2-3 days).
- Open the blue clamp on the outer retaining plate and pull it back far enough that the puncture site and bottom of the retaining plate can be cleaned thoroughly.

Instructions for use: Freka Pexact II, 15 FR

- Clean puncture site, feeding tube and fixation plate with warm water and mild soap. Volatile products are preferred to minimise the contact time with the tube.
- Dry the puncture site thoroughly. If appropriate, a split compress can be placed under the fixation plate.
- Rotate the tube daily 360° for tube mobilisation.
- Thorough aftercare is recommended in patients with severe cachexia, polypathia and poor general condition as well as for those patients who have suffered from diabetes for many years, as these patients are at increased risk of infection.

Important information

- The skin around the puncture site should be routinely checked for redness, swelling and granulating tissue.
- In case of healing disorders like induration or tenderness, and if food and/or secretions escape from the stoma, a healthcare professional must always perform an examination.
- The Gastropexy sutures should be removed only after a complete wound-healing of the stoma.
- Regularly move the tube clamp to avoid material damage of the tube.

Duration of use

It is recommended to replace the balloon tube after 90 days. The balloon tube can be replaced by the Freka GastroTube or Freka Belly Button.

Aftercare instructions

Before and after each administration of nutrition and medication, flush the tube with 20 mL lukewarm water. Use an ENFit syringe.

Important information

- Fruit tea or juice is not recommended. In case of administration do not mix with nutrition to avoid tube blockage.
- In case of blockage, the balloon tube must be replaced. Do not use high pressure or any kind of introducer to clear blockage as this could lead to tube perforation.
- The fill volume of the balloon should be regularly checked by a healthcare professional.
- To do this, gently push the balloon tube into the stoma. Attach a 5 mL luer slip syringe to the orange balloon valve and withdraw the fluid.
- If there is less than 5 mL, check the orange valve for leakages. Check the fill volume again in 24 hours.
- Refill the balloon with 5 mL of sterile water or boiled and cooled water.
- In case of repeated volume loss after 24 hours or leakages of the valve, the balloon tube must be replaced.

Instructions for use: Freka Pexact II, 15 FR

Important information

- When the balloon is empty, it is absolutely essential for the tube to be held and fixed in position to prevent it slipping out.
- The maximum filling volume of 5 mL for the balloon shall not be exceeded.
- If the balloon tube is inadvertently removed, a doctor must be consulted immediately as the stoma can close within 24 hours. A new balloon tube must be placed. Check the sutures for tight fixation.
- Do not move the patient.
- Insert a balloon tube of the same size and confirm that it is in the correct position endoscopically or by x-ray.
- Check the sutures carefully to ensure a secure fixation of the gastric wall to the abdominal wall.

Application of nutrition

After placement a fasting period of at least 1-2 hours is recommended. Enteral nutrition should be started gradually. Pump controlled continuous feeding is recommended with dedicated enteral feeding pumps only. Connect the giving set to the balloon tube and start feeding. After administration of nutrition and flushing, close the tube clamp and disconnect the giving set. Close the tube with the cap and open the tube clamp again.

Application of medication

Preferably administer dissolved medication via the medication port of the giving set or directly via the ENFit connector of the balloon tube. Liquid medicines are preferred.

Important information

- Before and after each administration of medicine, the balloon tube must be flushed thoroughly with 20 mL of lukewarm water.
- Use an ENFit syringe to administer medication.
- Do not mix medication, in particular antacids or any other fluids with enteral nutrition to avoid tube blockage. For any questions contact your doctor or pharmacist.

Removal of the balloon tube

The balloon tube must not be replaced until the stoma canal has healed completely. Otherwise there is a risk of injury.

- Pull back the external fixation plate and connect a 5 mL luer slip syringe to the orange lateral valve and withdraw the fluid of the balloon completely.
- Gently withdraw the balloon tube out of the stoma while holding the abdominal wall with the other hand and exert a light counter pressure.
- Apply a plaster. A fasting period is not necessary. The stoma closes within 24 hours under normal conditions. Medical supervision is recommended until the stoma is completely closed.

Instructions for use: Gastropexy device

Checking the function of the gastropexy device

Carefully remove the gastropexy device from its packaging, and inspect it for possible damage or defects. Inspect:

- 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 fixation sutures provide adequate fixation of the gastric wall to the abdominal wall. Decide on a case-by-case basis whether three or 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 (approximately 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 - at least 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 runs 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.

Ordering information

Freka Pexact II with Insertion Kit

Direct Puncture Gastrostomy with secure and reliable Gastropexy.

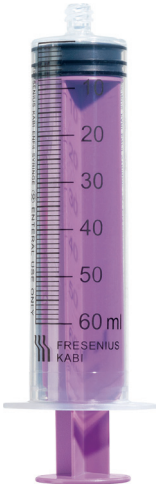
Article code:
7601365

Sales Unit: 1 x 1

Freka Universal Funnel Adapter, ENFit

For compatibility of:
- ENLock sets to ENFit feeding tubes
- ENLock syringes to ENFit feeding tubes
- For decompression with drainage bags

Article Code: 7755695
Sales Unit: 1 x 15



Freka Connect ENFit 60mL Syringe

Administration of nutrition and liquids.
Compatible to male ENFit connectors.
Sterile, single packed.

Article code: 9000786
Sales Unit: 50 x 1

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