

Freka® GastroTube

Gastric replacement balloon
tube for use within a fully
formed and healed stoma

Product Code: 7755648



15
FR

**Product features and insertion technique
for healthcare professionals**



freka.com.au

Product features

The Freka GastroTube is a silicone 15 FR gastric replacement balloon tube for use within a fully formed and healed stoma designed for intragastric long term nutrition.

It can be used as a **replacement for any fully formed stoma from 14 FR to 16 FR.**



Biocompatible

Tube made of biocompatible silicone.

Freka ENFit & funnel connectors

- Gastrotube ENFit insert allows connection to a wide array of compatible ENFit accessories for feeding.
- Removal of the ENFit insert allows the funnel connector to be adapted for decompression or other funnel accessory connections.



Tube clamp

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

Easy placement

- Plastic mandrin for shaft stabilisation during placement.
- Placement possible via Seldinger technique.

Features

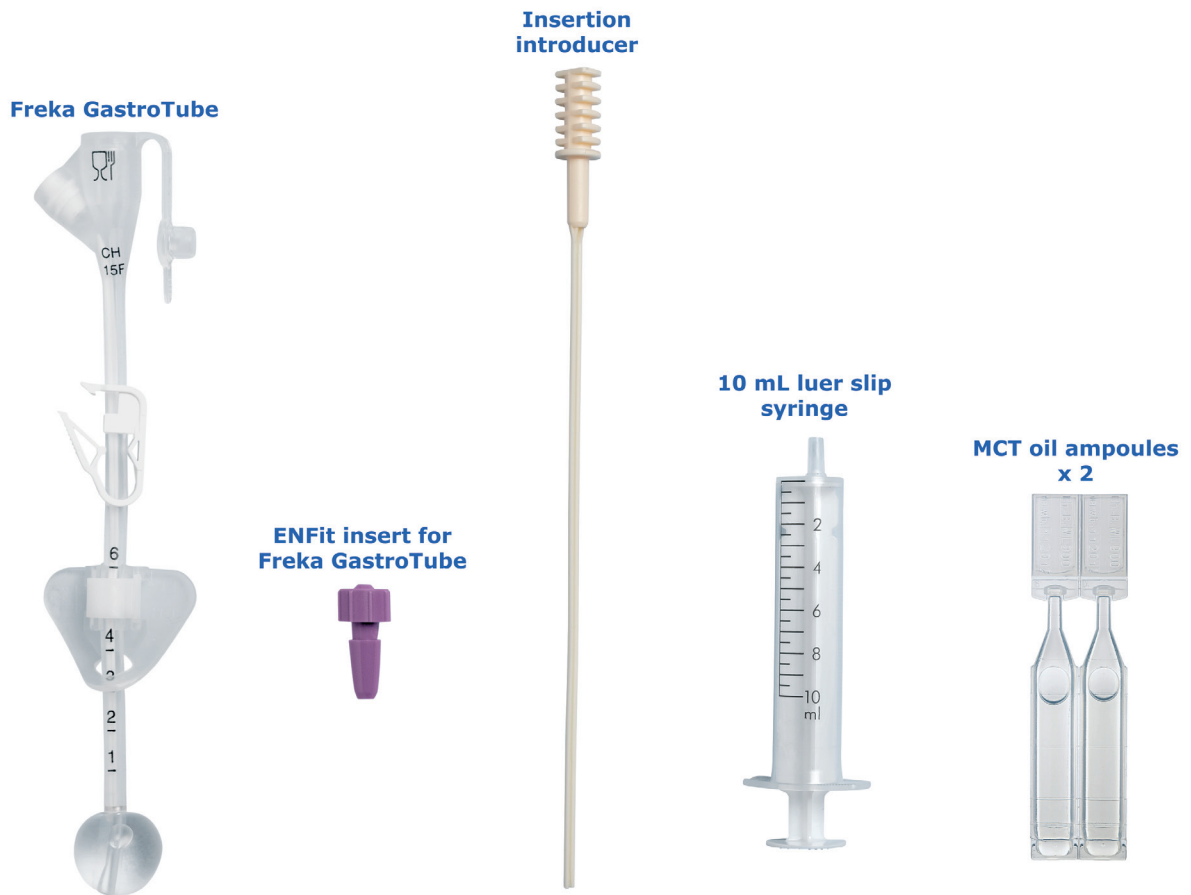
- X-ray contrast strip. Interval markings every 1cm.
- Comfortable silicone retention plate.
- Balloon capacity 5 - 7 mL.
- Flat, rounded terminal opening.

Longevity

Balloon durability has been shown to last 154.8 days \pm 10.2 days¹.

¹ Villela, E.L., et al., Endoscopic gastrostomy replacement tubes: long-term randomized trial with five silicone commercial models. Clin Nutr, 2014. 33(2): p. 221-5

Included in the kit



Freka GastroTube 15 FR single lumen gastric replacement balloon tube

13 cm, 15 FR gastric tube.

ENFit insert

ENFit insert to allow connection of ENFit accessories to the Freka GastroTube.

Insertion introducer

Tool to be used as an aid during insertion.

Luer slip syringe

10 mL luer slip syringe for balloon testing and inflation.

MCT oil

Two ampoules of MCT oil for lubrication.

Insertion technique

Optional endoscopically monitored gastric insertion

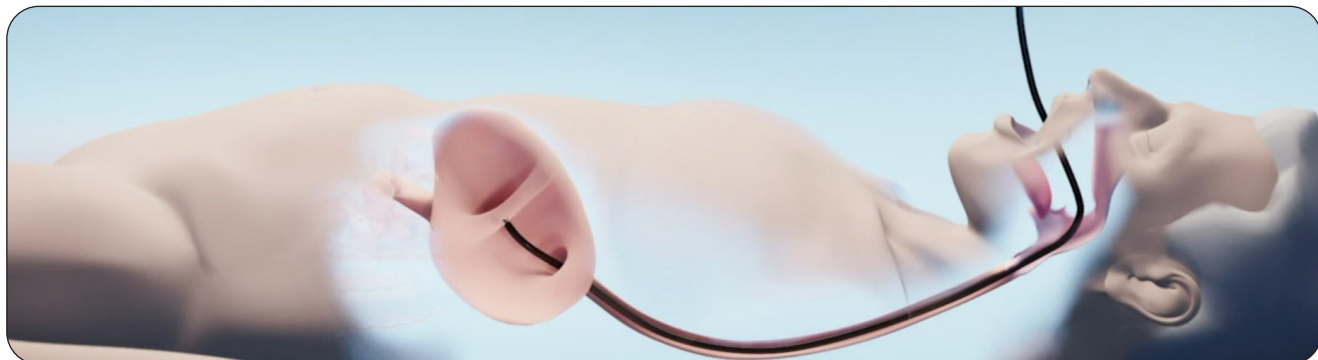


Fill the balloon of the Freka® GastroTube with 5 ml of isotonic physiological saline or sterile water through the valve on the side using a luer slip syringe and check visually for leaks.



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

Optional endoscopically monitored gastric insertion



Insert the gastroscope into the stomach and insufflate with sufficient air. Remove existing gastrostomy tube using approved procedure if present.

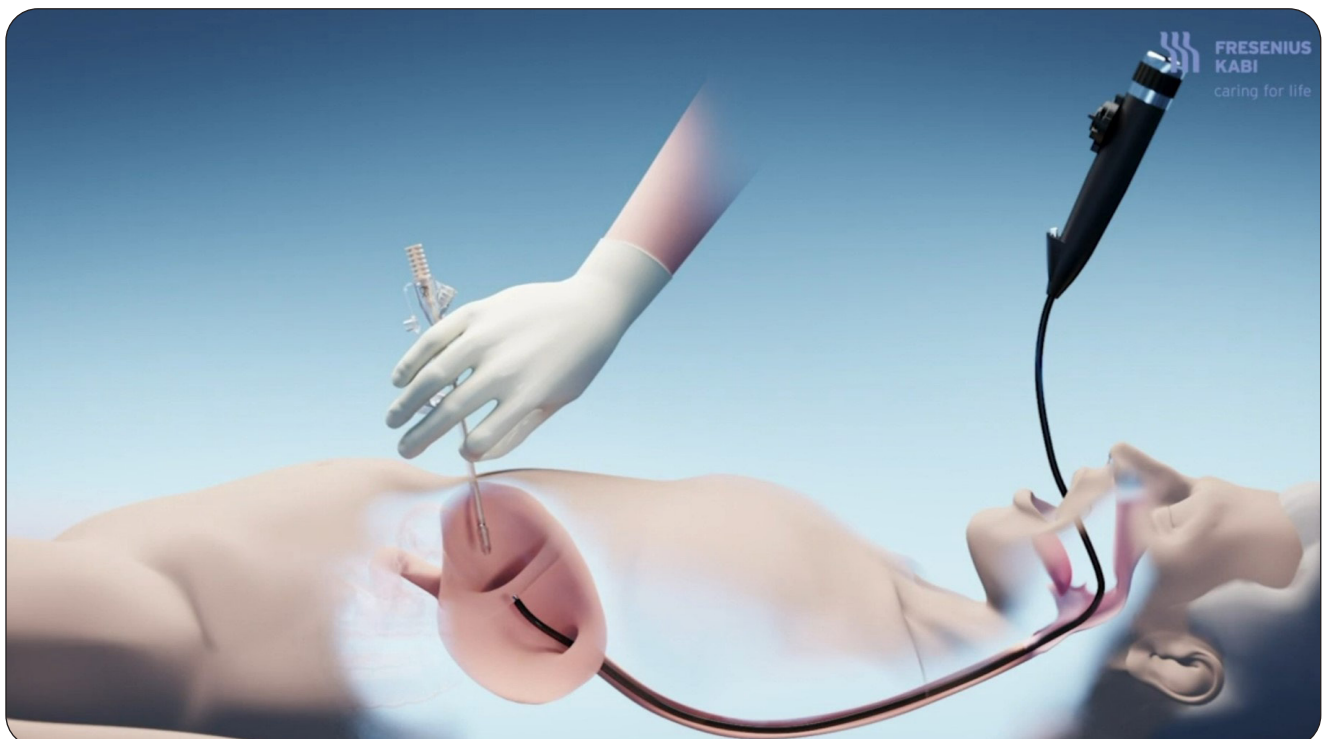


The balloon of the Freka GastroTube is moistened with a lubricant.

Optional endoscopically monitored gastric insertion



Grip the shaft slightly above the balloon.



The tube is inserted through the stoma into the stomach with slight rotating movements. If there is any resistance do not move it forcefully.

Optional endoscopically monitored gastric insertion

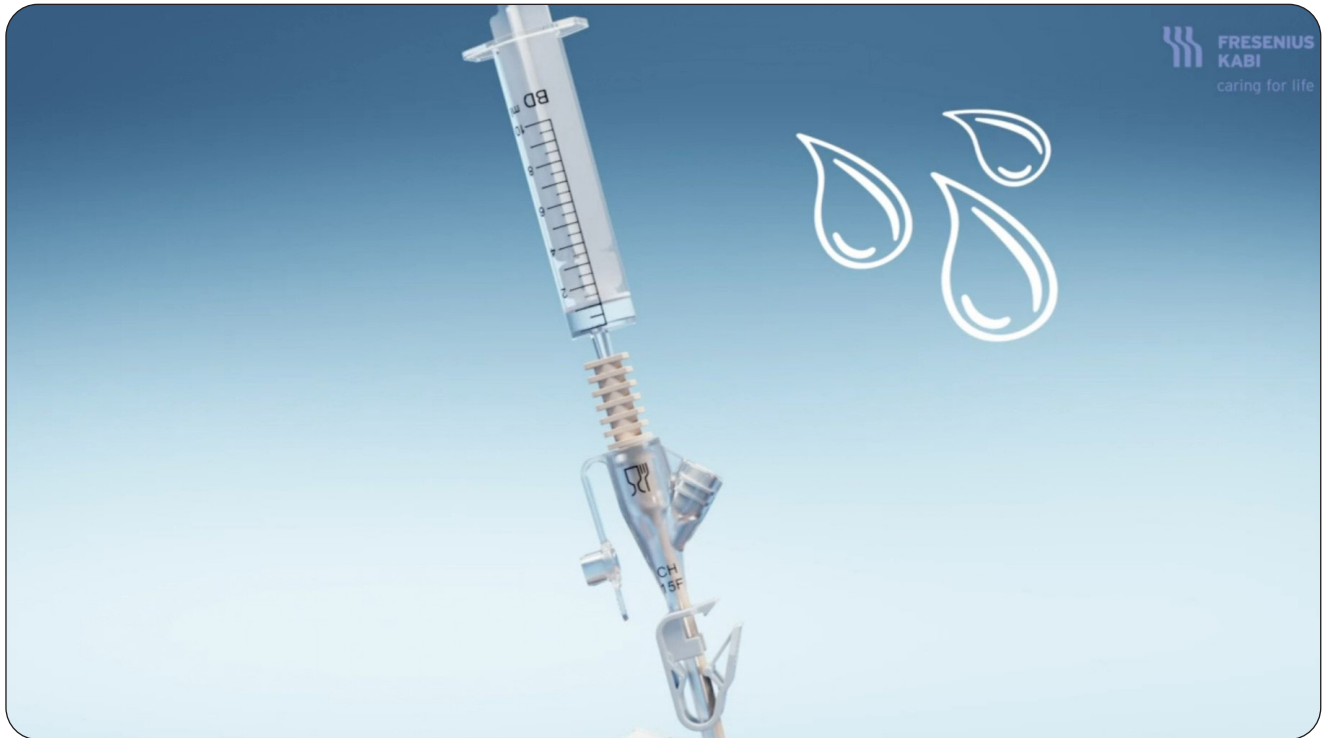


The skin of the balloon of the Freka® GastroTube should be visible in the stomach with the endoscope before the balloon is filled. Insert a luer slip syringe into the lateral valve and inject approximately 6 mL of saline solution or sterile water.

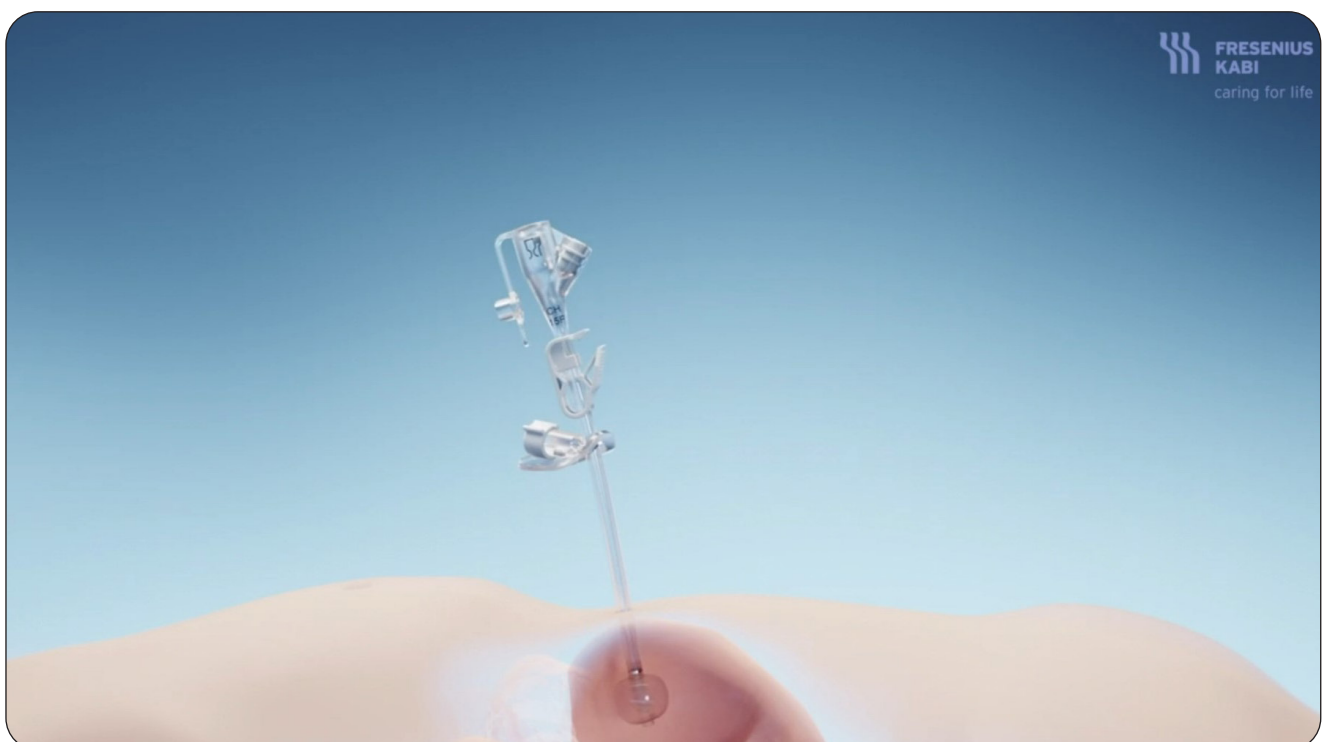


The balloon will now inflate. Record the amount used to fill the balloon.

Optional endoscopically monitored gastric insertion



To assist with the removal of the insertion introducer insert water in the opening of the introducer.



The insertion introducer is then removed.

Optional endoscopically monitored gastric insertion



The Freka GastroTube is gently pulled back until a slight resistance is felt and the outer retention plate moved down to the stoma site.

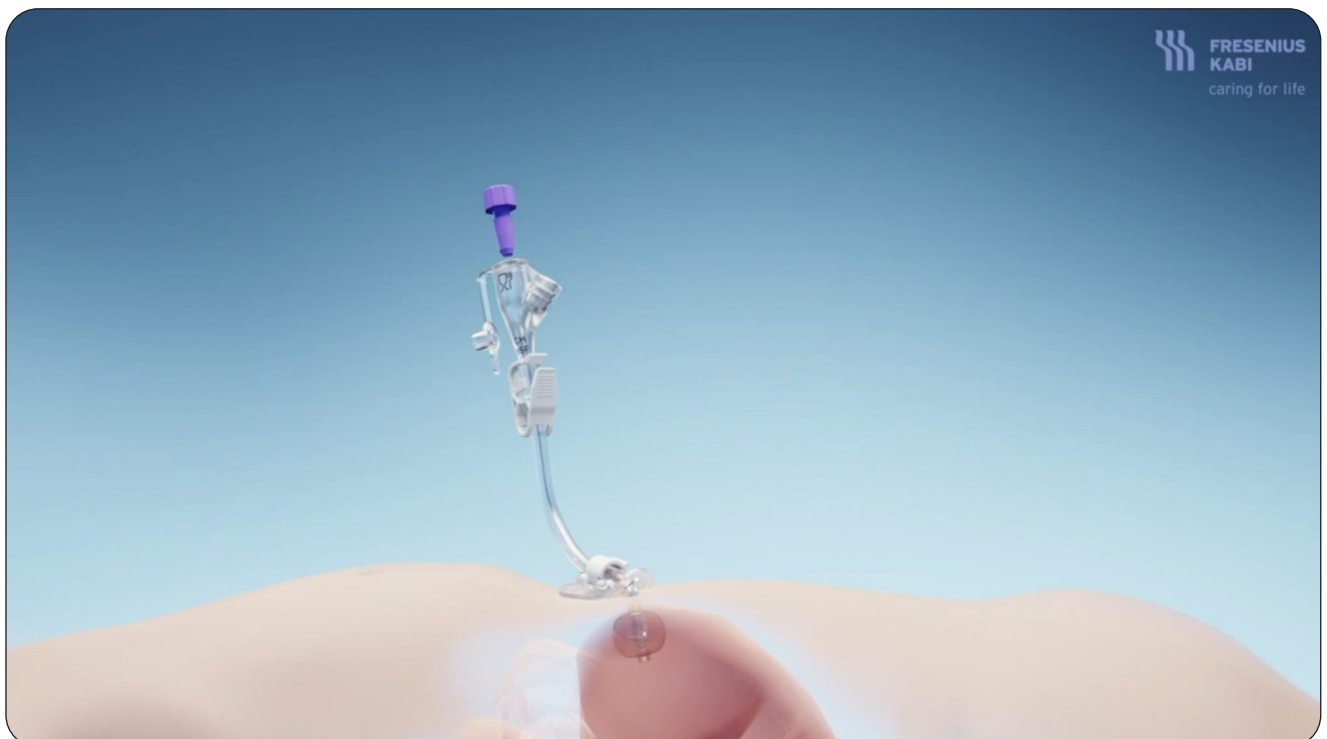


The retention plate clamp is closed after the tube has been inserted.

Optional endoscopically monitored gastric insertion



The funnel of the Freka GastroTube must be clean and dry especially if the MCT oil was used.



The ENFit insert is pushed all the way in using a slight twisting movement.

Optional endoscopically monitored gastric insertion



The Freka GastroTube cap is closed however the clamp remains open.

Check using endoscope that the Freka GastroTube is correctly positioned.

If endoscopic access is not possible, the Freka GastroTube can also be inserted without an endoscope. In this case, correct positioning should be checked using X-ray.

Careful aftercare and maintenance of the Freka GastroTube 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

Indications

- long-term intragastric feeding
- gastric decompression
- for use in a healed stoma tract.

Important information

The Freka GastroTube can be inserted with or without the use of the Seldinger method. The Seldinger method is safer and is therefore particularly recommended in the case of:

- a crooked stoma tract
- a very narrow stoma tract
- a very long stoma tract
- patients where there is a risk of fistulas forming (e.g. patients with cystic fibrosis).

The Freka Seldinger wire for percutaneous replacement systems is available separately (see ordering information).

Contraindications

- stoma not completely formed and healed
- stoma larger or smaller than 15 FR (+/- 1 FR)

Important information

The Freka GastroTube may only be inserted as a replacement system via a well-formed and fully healed stoma tract, no earlier than 4 weeks after initial positioning of a PEG.

In patients who are undernourished or are being treated with steroids, the stoma often takes longer than 4 weeks to heal completely.

Checking the function of the Freka GastroTube before use

Fill the balloon of the Freka GastroTube with 5 mL of isotonic physiological saline or sterile water through the valve on the side using a luer slip syringe and check visually for leaks. Knead the balloon gently between the fingers. Then aspirate all the fluid back out of the balloon.

Important information

After checking the function, make sure the balloon is completely empty. The skin of the balloon needs to abut the shaft as closely as possible in order to avoid injuring the stoma during insertion.

Instructions for use

Replacing a PEG tube with the Freka GastroTube

The Freka GastroTube can be inserted with or without the use of the Seldinger technique.

Removal of the PEG

- Insert the gastroscope into the stomach and insufflate sufficient air.
- Push the PEG tube a little way into the stomach.
- Grip the internal retention plate of the PEG, preferably using a polypectomy loop or two-armed gripping device.
- Pull on the feeding tube again and cut off PEG tube above the abdominal wall.
- When using the Seldinger technique insert the soft end of the Seldinger wire into the lumen of the stomach through the feeding tube which has been cut off.
- As the PEG is withdrawn, the Seldinger wire is advanced so that it lies in the stoma channel as a guide.

Inserting the Freka GastroTube

- Wet the balloon of the Freka GastroTube with lubricant.
- Insert the Freka GastroTube through the stoma and into the stomach with slight rotating movements.
- Using the Seldinger technique, thread the Freka GastroTube with the stabilizing introducer over the Seldinger wire from the end of the balloon. Then insert the Freka GastroTube through the stoma and into the stomach with slight rotating movements.
- The skin of the balloon of the Freka GastroTube should be visible in the stomach with the endoscope before the balloon is filled.
- Use the luer slip syringe to fill the balloon with 5 - 7.5 mL of isotonic physiological saline or sterile water through the valve at the side.
- Record the amount used to fill the balloon.

Important information

- Hold the Freka GastroTube approx. 2 - 3 cm above the balloon when pushing it into the stoma.
- Under no circumstances may force be used to advance the Freka GastroTube. Otherwise, there is the risk of perforation.
- Under no circumstances fill the balloon with air. Filling with air impairs life span and reduces the amount of time the tube can be left in place! The maximum capacity of the balloon of 7.5 mL may not be exceeded.

Instructions for use

- Remove the Seldinger wire if used.
- Carefully remove the insertion introducer from the Freka GastroTube. For removal insert water in the opening of the introducer. In the case that MCT-oil should be necessary, the funnel of the Freka GastroTube must be cleansed of grease completely afterwards.
- Thoroughly clean and disinfect stoma, retention plate and GastroTube and allow to dry.
- Pull on the tube using moderate force.
- Next, advance the external retention plate as far as the stoma, then insert the Freka GastroTube in the guide of the retention plate and fix in position by closing the clip.
- Withdraw the inner retention plate of the PEG with the gastroscope.

Important information

The inner part of the funnel of the Freka GastroTube must be dry and free of grease.

- Now insert the purple ENFit Insert by slightly turning it into the funnel as far as possible until it is fixed and can not be removed. The ENFit Insert remains in the Freka GastroTube and must not be removed.
- Close the Freka GastroTube with the closing cap.

Important information

Check using endoscope that the Freka GastroTube is correctly positioned.

If endoscopic access is not possible, the Freka GastroTube can also be inserted without an endoscope. In this case, correct positioning should be checked using X-ray.

- Pull only gently on the Freka GastroTube. The outer tensile strain should not be too great, otherwise pressure necroses can form.

Replacing a button or a balloon tube with the Freka GastroTube

- Remove the current Button/ Balloon tube according to the instruction of the manufacturer.
- Place the Freka GastroTube as described.
- When using the Seldinger technique, insert the soft end of the Seldinger wire in the current Button/ Balloon tube before removing it.
- The Seldinger wire remains in the stoma tract.
- Place the Freka GastroTube as described.

Instructions for use

Feed administration and decompression

Feed administration can start immediately after the Freka GastroTube has been inserted.

- Open the sealing cap and close the tube clamp on the Freka GastroTube. Connect the giving set with the Freka GastroTube and open the clamp.
- Once feeding and flushing are complete, remove the giving set and close the Freka GastroTube with the sealing cap. The ENFit insert remains in the Freka GastroTube.
- For decompression the Freka GastroTube can be connected directly to an ENFit syringe or to a decompression/drainage bag if necessary with the help of the Freka Universal Funnel Adapter (see ordering information).

Aftercare of Freka GastroTube

- The feeding channel of the Freka GastroTube must be flushed with 20 mL of lukewarm water before and after every feeding operation - at least once a day - preferably using a ENFit syringe (Freka Connect).

Important information

No fluids containing acid, especially fruit teas or fruit juices, should be used in conjunction with tube food, as they can result in constituents of the food to coagulate. In case of blockage, the Freka GastroTube should be changed. The lumen may under no circumstances be cleared under high pressure or using an introducer.

Care of the stoma

- Undo the clamp on the external retention plate and pull the plate back.
- Clean the puncture site and the underside of the retention plate daily with warm water and mild soap. Then dry thoroughly. If necessary, a thin dressing can be placed under the retention plate.
- The Freka GastroTube should be rotated 360° in the stoma every day to maintain freedom of movement.
- Check entry point daily for redness, swelling and granulation tissue. If skin changes are found, consult the doctor.

Important information

- If the stoma leaks or if there is hardness or pain on palpation around the stoma, a doctor's examination is essential.
- If the Freka GastroTube becomes noticeably loose, the fill level of the balloon should be checked. If there is much less than the anticipated fill quantity in the balloon, check that the outer valve on the side is not leaking by checking for escaping fluid. In any event, the volume check must be repeated after no more than 24 hours. If the fill quantity is once again below what it should be, or if leaks have occurred at the valve, the Freka GastroTube needs to be replaced.
- If the Freka GastroTube is removed inadvertently, a doctor should be seen at once, as the stoma can close up quickly.

Instructions for use

Administration of medicines

If at all possible, medicines should be administered in solution via the medication port on the giving set or using an ENFit syringe. Liquid formulations (drops or syrup) are preferred.

Important information

The Freka GastroTube must be flushed with 20 mL of lukewarm water before and after every administration of medicines, preferably using an ENFit syringe.

Medicines, especially antacids, may under no circumstances be administered mixed in with food. If in doubt, consult the supervising physician or a pharmacist.

Duration of use

The Freka GastroTube is designed to have a life span of several months. Frequent administration of alcoholic drinks can result in material defects which require the tube to be changed, even if it has only been in place a short time. The Freka GastroTube must be adequately flushed every time it has been used for administration. Material defects caused by medicines can be largely avoided if the Freka GastroTube is adequately flushed before and after every administration of medicines.

How to remove the Freka GastroTube

The Freka GastroTube is removed as follows:

- Open the white clip of the external retention plate.
- Attach the 10 mL luer slip syringe to the valve on the side of the Freka GastroTube and empty the balloon completely by drawing up the fluid.
- Carefully withdraw the Freka GastroTube out of the stoma, holding the abdominal wall steady with the other hand.
- Then apply an adhesive dressing. A starvation period is not necessary.
- The supervision of a physician is recommended until the stoma has closed up completely.

Notes

[illegible]

Ordering information

Freka GastroTube



Insertion introducer



ENFit insert for Freka GastroTube



10 mL luer slip syringe



MCT oil ampoules x 2



Freka Cone Adapter, ENFit

Adaptor for connection of a female ENFit connector with a funnel feeding tube or connection of an ENFit syringe for aspiration of the gastric lumen on the Freka Gastrotube.

Article code: 7751562

Sales Unit: 15 x 1



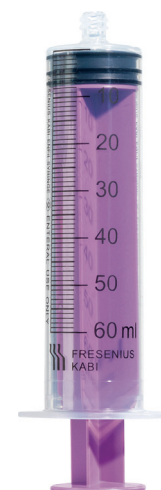
Freka Universal Funnel Adapter, ENFit

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



**FRESENIUS
KABI**

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai, NSW 2080 Australia
Ph: 1300 732 001
PM2024.1958 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 MR10471