

Freka[®] Belly Button

Percutaneous low profile feeding tube
for long-term enteral nutrition



Product features and insertion techniques for healthcare professionals

Direct placement technique
Seldinger placement technique
Device removal

12 -> 24
FR



freka.com.au

Product features

Freka Belly Button ENFit

The Freka Belly Button is a percutaneous low profile feeding tube for long-term enteral nutrition with a range of ENFit extensions.

It is a gastric replacement system for use within a fully formed and healed stoma tract.

Sizing options

12/14/16/18/20/24 FR

1/1.5/2/2.5/3/3.5/4/4.5/5 cm lengths

Note, some sizes may need to be ordered on request. See back page for common options.

Biocompatible

Tube and fixation plate made of biocompatible medical grade silicone.

Flat distal opening

Flat distal opening to avoid mucosal irritation.

Anti-reflux valve

Anti-reflux valve to prevent backflow.

Latex free	Luer free	PVC free	DEHP free
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Innovative insertion

- Introducer tool for more stability during placement.
- Seldinger technique can be used if required with included introducer.

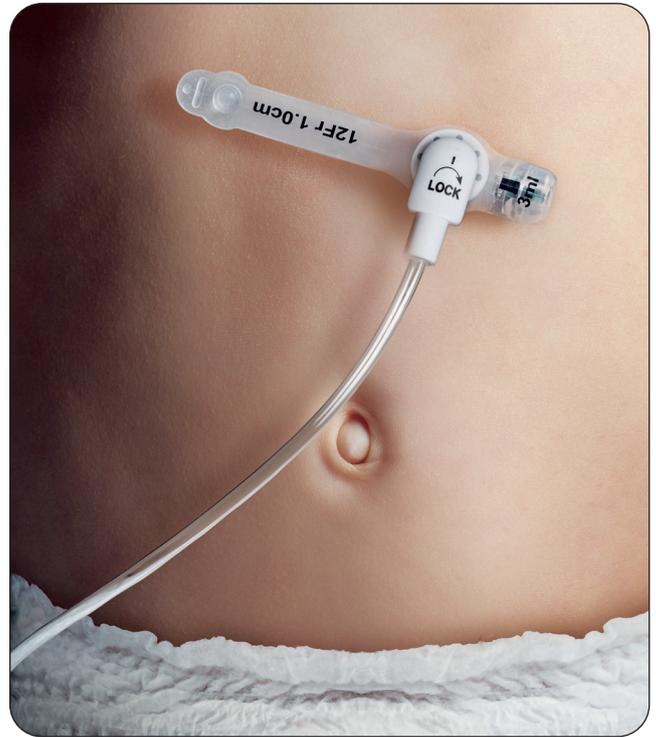
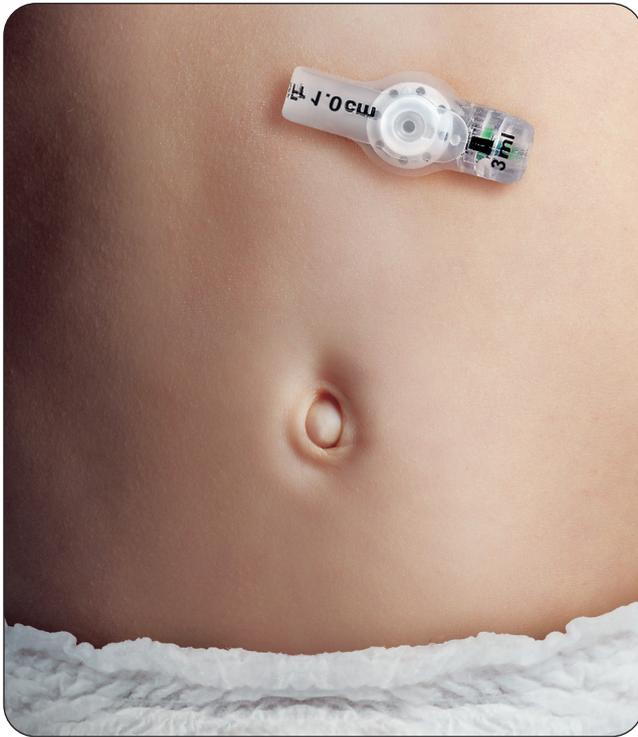
ENFit extension sets

- 30cm straight option.
- 30cm right angled option.
- Both options can be lengthened with either a 30cm or 120cm ENFit extension set.

Discreet, comfortable and simple

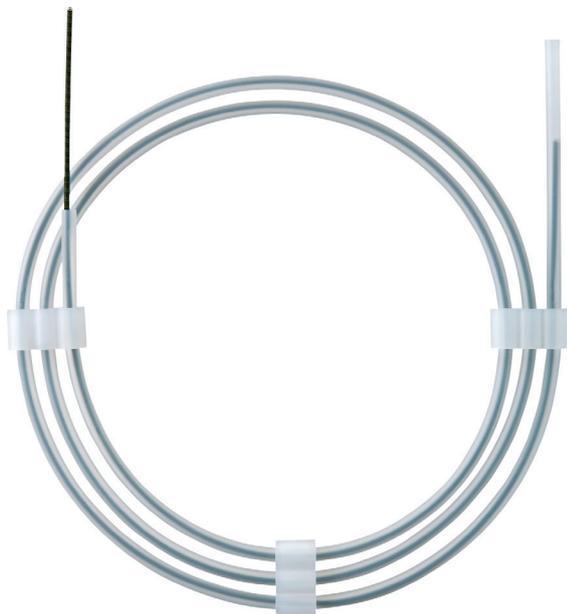
Discretion and comfort for your patients

The super low profile of the Freka Belly Button compared to other brands available in the market and comfortable silicone design allows your patients to discreetly attend to their feeding needs.



Quick to insert. Easy to replace.

The Freka Belly Button comfort kit comes with Seldinger technique introducers to stiffen the shaft during placement and act as guidance for the Seldinger wire.



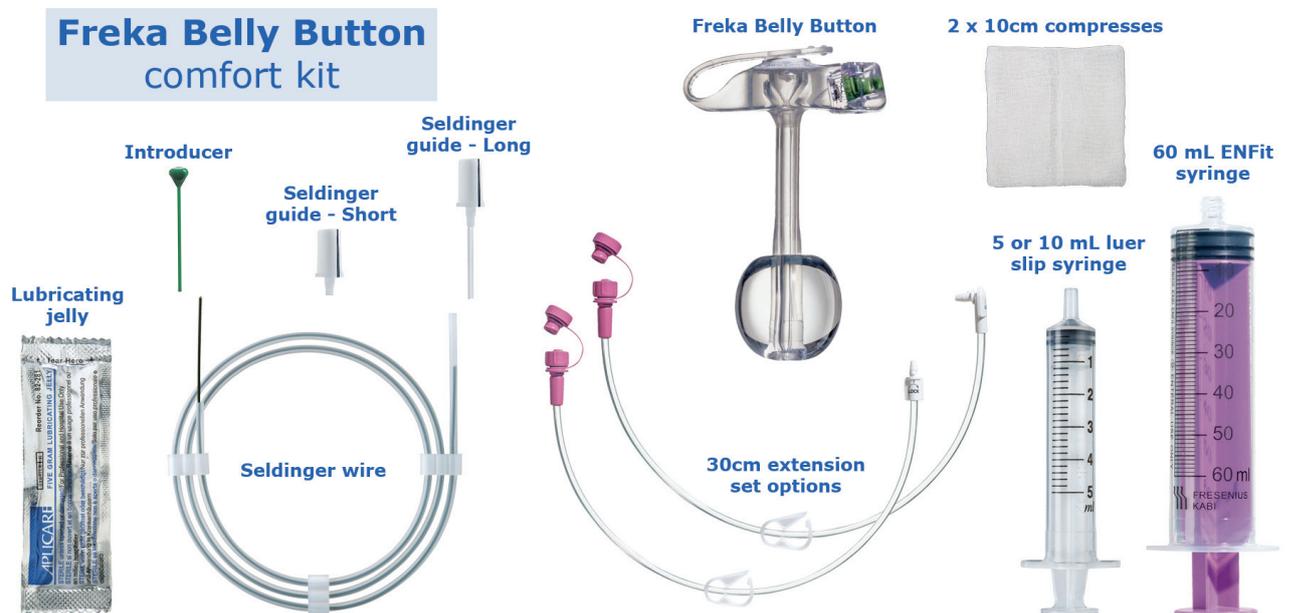
Using the Seldinger technique and wire guidance, the Freka Belly Button can find its way more easily, especially in stoma tracts, which might be:

- crooked
- very narrow or very long
- with risk of fistula formation e.g. in cystic fibrosis.

By using the Seldinger technique and included tools within the Freka Belly Button kit, stoma tract penetrations can be minimised. The soft tip of the Seldinger wire also minimises mucosal irritations.

The Seldinger technique is recommended in both hospital and home care settings.

Kit contents: Freka Belly Button Comfort Kit



Freka Belly Button

Gastric replacement system for use with a fully formed and healed stoma tract.

Seldinger wire

Allows the use of the Seldinger over the wire technique.

Seldinger guides

Short and long guides to assist in Seldinger placement.

Introducer

Used to stiffen the shaft of the Belly Button for improved control during insertion.

Lubricating jelly

10cm compresses: Quantity = 2

30cm extension sets

Straight and right angled options included. Allows seamless feeding to begin after insertion.

Luer slip syringe

5 mL luer slip syringe used for balloon inflation and deflation.

ENFit syringe

60 mL ENFit syringe allows for feeding through the extension set after insertion.

Insertion technique

Direct placement technique



The existing tube must first be removed according to the respective instructions for use.

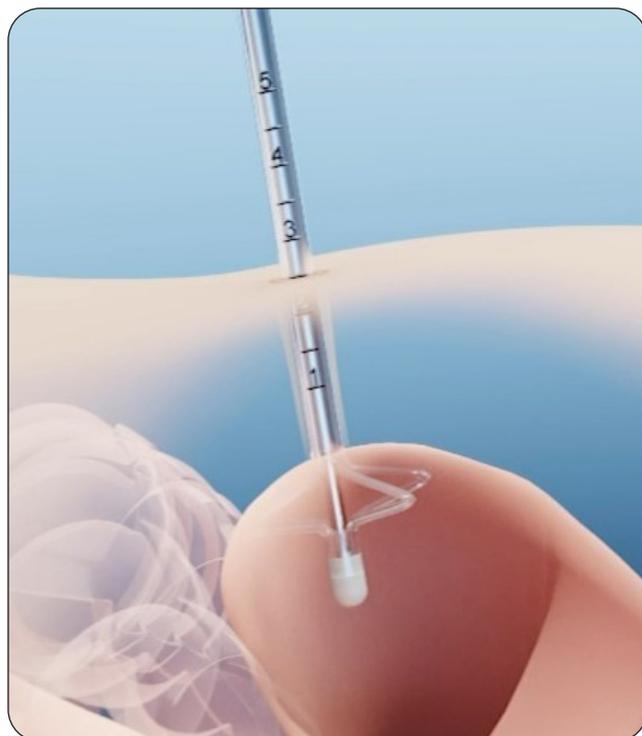


Before placing a Freka Belly Button the appropriate Button must be selected. The FR size should correspond to the size of the tube already in place.

Direct placement technique

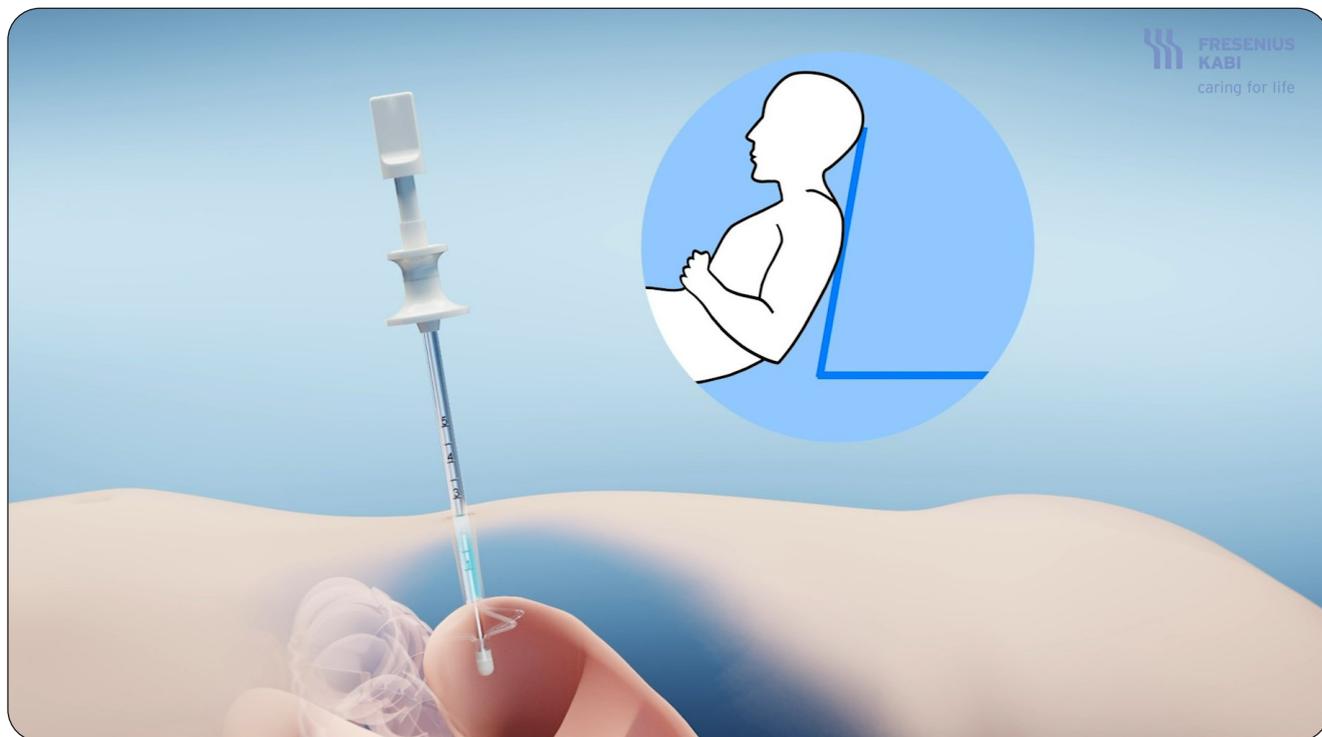


The stoma measuring device is carefully pushed forward through the stoma into the stomach.

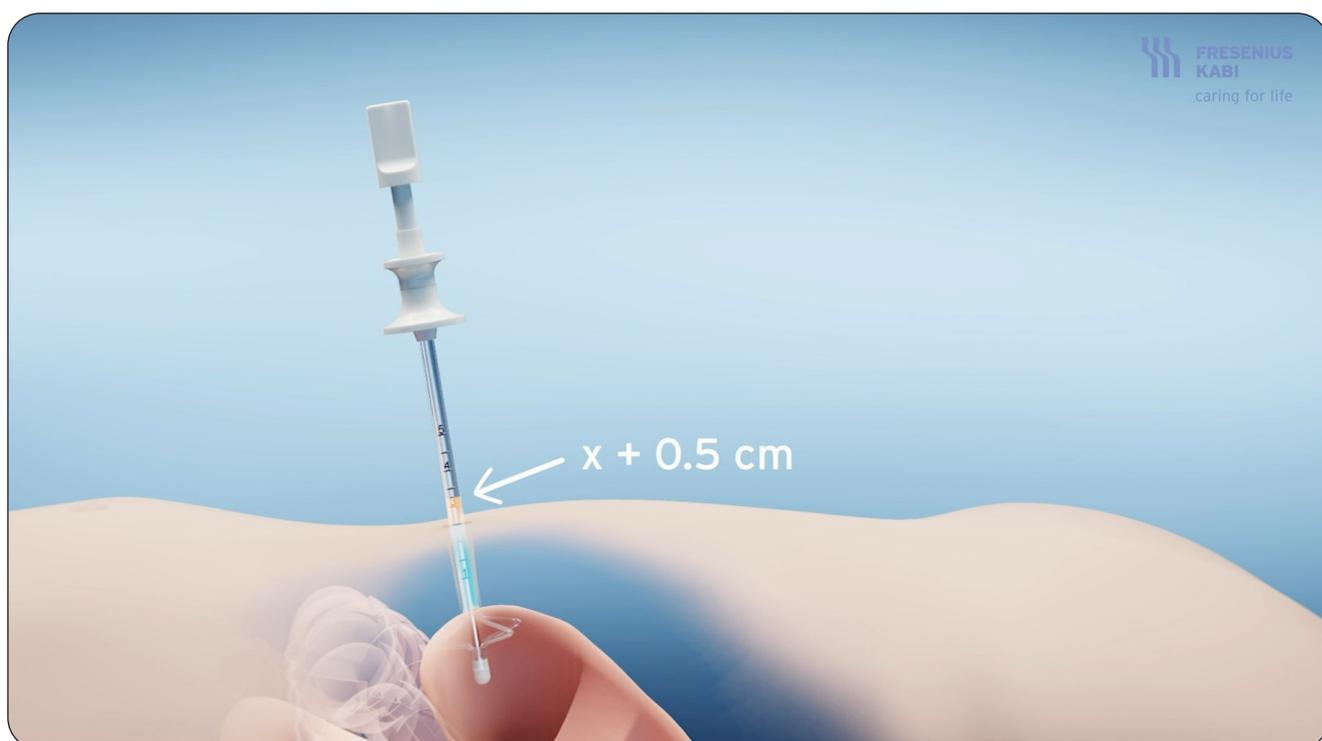


Pulling the handle unfolds a retention mechanism. The stoma measuring device is withdrawn until a slight resistance is felt.

Direct placement technique



Read the stoma length. This should be checked with the patient in a lying and slightly upright position.

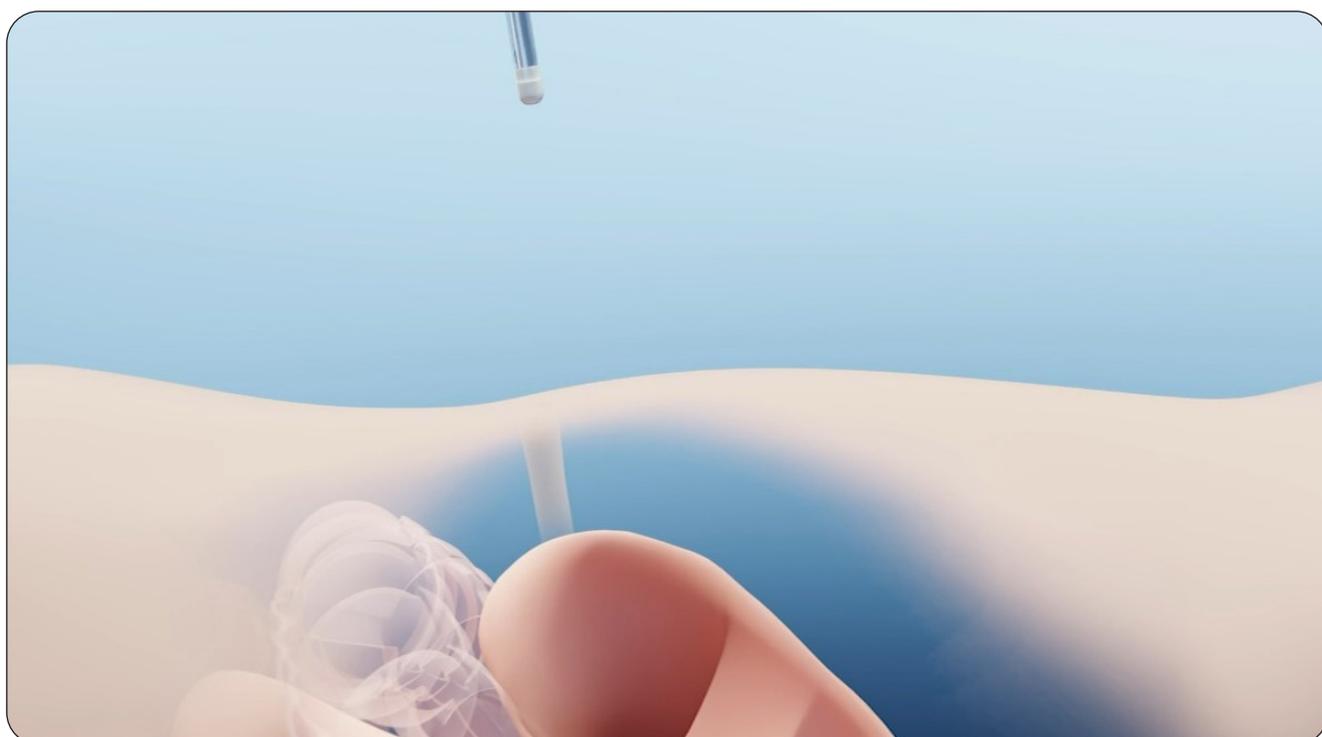


A button with a shaft length that is 0.5 cm longer than the maximum stoma length is optimal.

Direct placement technique



The handle of the stoma device is pushed back in until the retention mechanism retracts.



The stoma measuring device is then removed from the stomach.

Testing the Freka Belly Button device before use



Filling volume table

Button FR Size	Filling Volume (mL)
12 FR	3.0 mL
14 FR	4.0 mL
16 FR	5.0 mL
18 FR	5.0 mL
20 FR	8.0 mL
24 FR	8.0 mL

Fill the luer slip syringe with the volume of sterile water or saline solution corresponding to the FR size as printed on the valve. Refer to the table above.

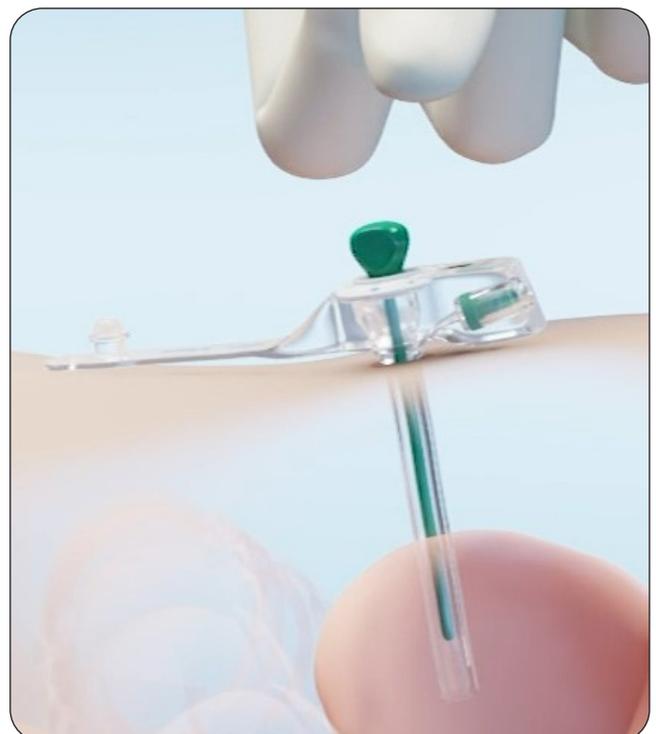


Visually check the balloon for leaks and then withdraw the liquid completely back into the syringe. Keep the syringe for later use.

Direct placement technique

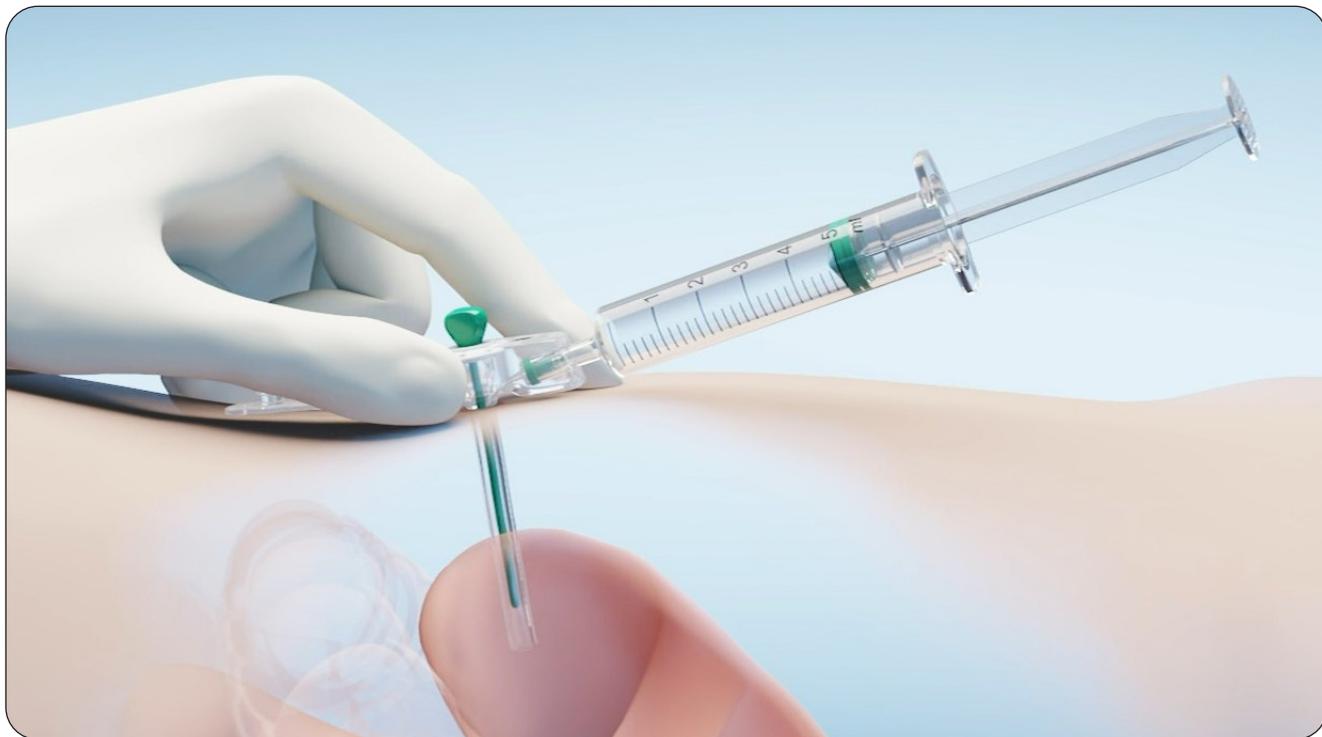


To stabilise the button shaft insert the green introducer into the central opening to aid in placement of the Button.

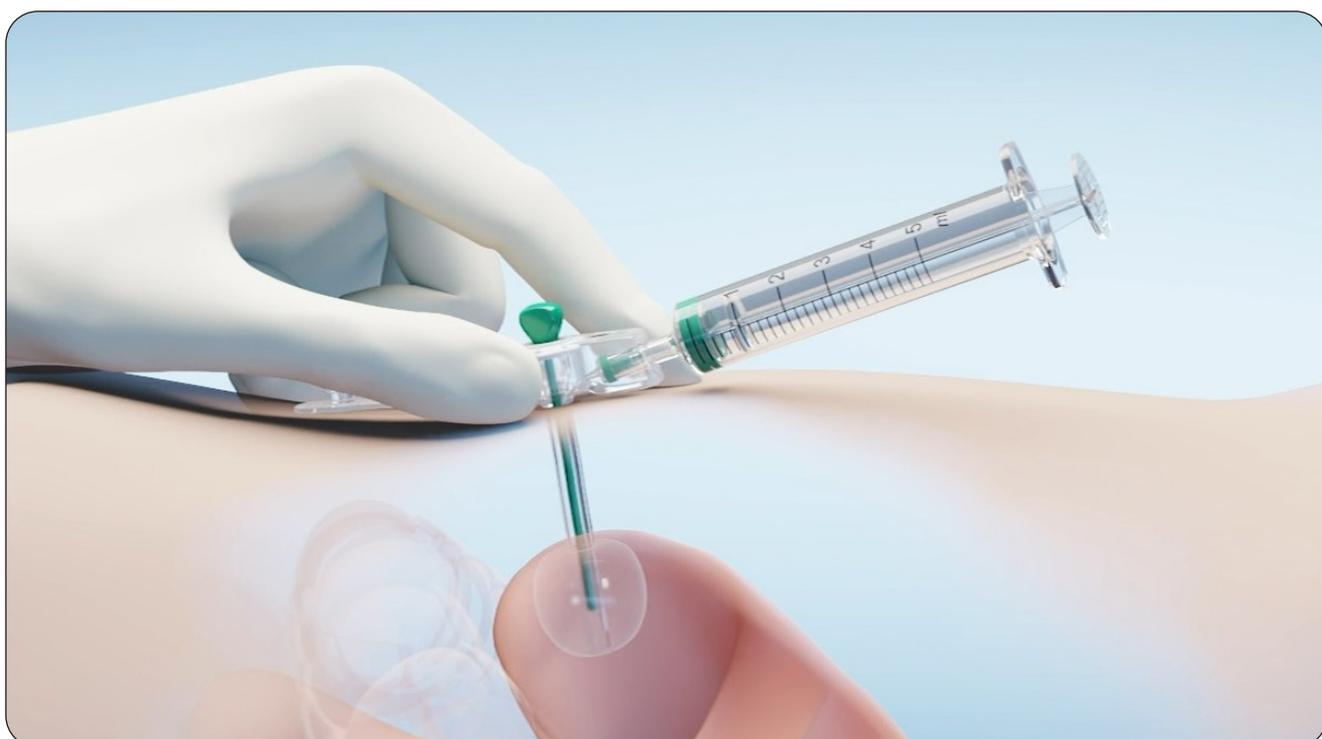


The balloon and the Button are moistened with the lubricant included in the kit. The Button is carefully inserted into the stoma tract with a slight twisting motion if required.

Direct placement technique

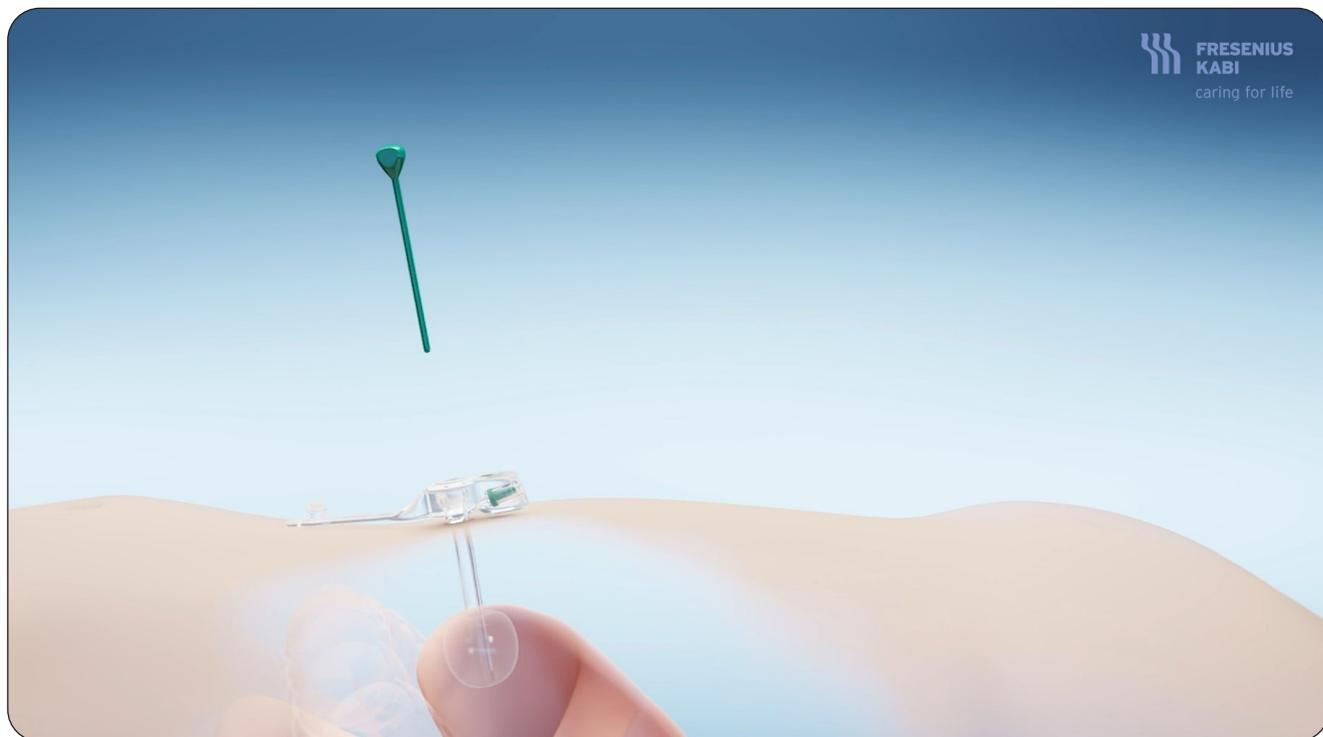


Secure the button by hand.



Fill the balloon with the luer slip syringe via the side valve. Use only the specified volume of liquid corresponding to the FR size in the table found previously in this document.

Direct placement technique



Remove the introducer.



Close the Freka Belly Button using the sealing tab on top. The Freka Belly Button must be able to rotate easily within the stoma. Feeding can be started immediately.

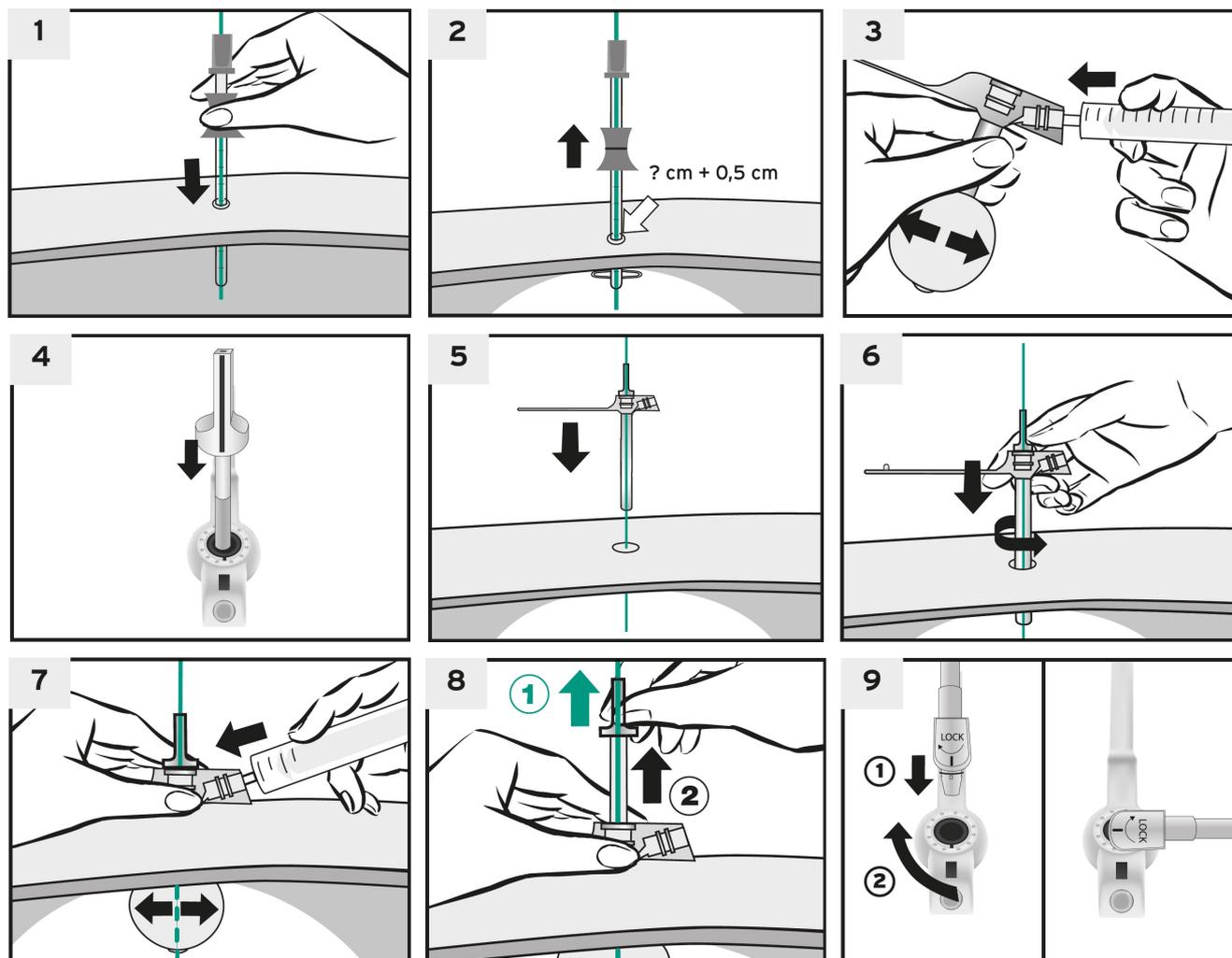
Direct placement technique



Careful aftercare and daily maintenance of the Freka Belly Button 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.

Seldinger technique



Using the **Seldinger technique** and wire guidance the Freka Belly Button can find its way more easily, especially in stoma tracts, which might be:

- crooked
- very narrow or very long
- with risk of fistula formation e.g. in cystic fibrosis.

Seldinger technique steps

1. Place the stoma length measuring device over the Seldinger wire as per the manufacturer's instructions and carefully advance into the stomach.
2. Measure the stoma length according to the instructions for use for the length measuring device.
3. Fill the balloon of the selected Freka Belly Button with the specified amount of fluid through the laterally mounted valve.

Seldinger technique

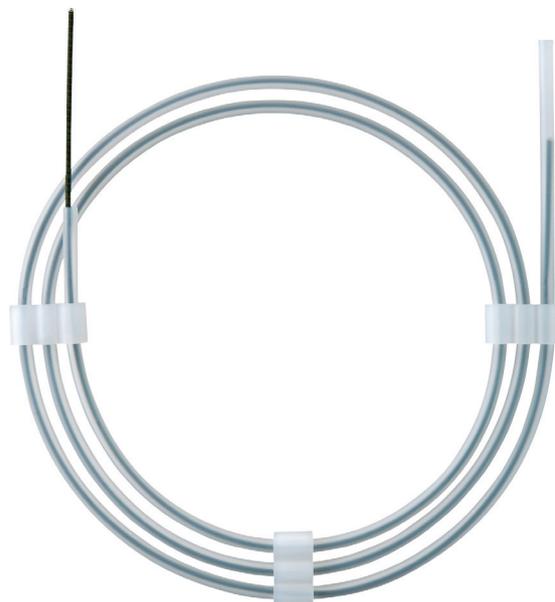
4. Advance the introducer in to the central opening of the Button (feeding port) so that the black markings on the handle and the opening lie on top of each other. The introducer is used to stiffen the shaft and to open the feeding valve for the Seldinger wire.
5. Thread the Button with the introducer onto the outer end of the Seldinger wire in the stoma without altering the position of the wire in the stomach.
6. Position the Button carefully, if necessary twisting slightly, intragastrically over the Seldinger wire until the head of the Button lies on the skin.
7. Secure the Freka Button manually. Fill the balloon with the specified amount of water by connecting the syringe to the lateral valve. Also take note of the filling volumes from the previous table.
8. Now first carefully withdraw the Seldinger wire and then the introducer from the Button and seal it with the sealing tab.
9. Open the sealing tab of the Button and advance the white connector from the Freka Button Extension Set into the central opening (feeding port). Make sure that the black markings on the connector and the opening lie on top of each other. Secure the adaptor in position by turning it 90° clockwise.

Note

For FR sizes ≤ 14 , the introducer for Seldinger technique contains no shaft due to the restricted internal lumen of the feeding channel. The introducer is only used to open the feeding valve for the Seldinger wire.

Filling volume table

Button FR Size	Filling Volume (mL)
12 FR	3.0 mL
14 FR	4.0 mL
16 FR	5.0 mL
18 FR	5.0 mL
20 FR	8.0 mL
24 FR	8.0 mL



Belly Button removal technique

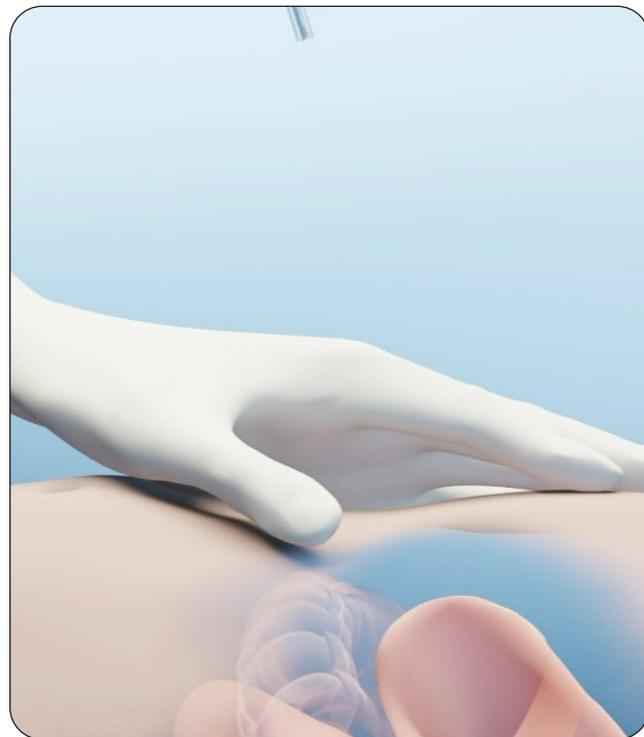
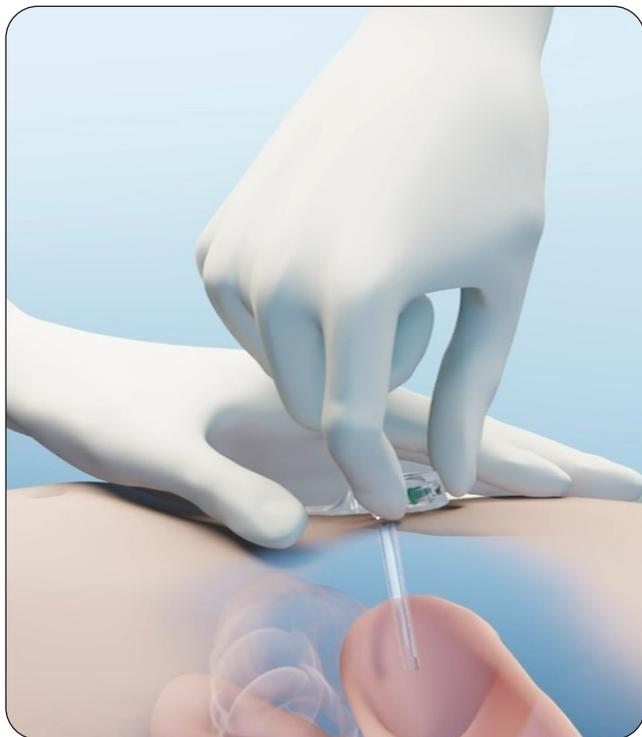


A luer slip syringe is attached to the side valve.

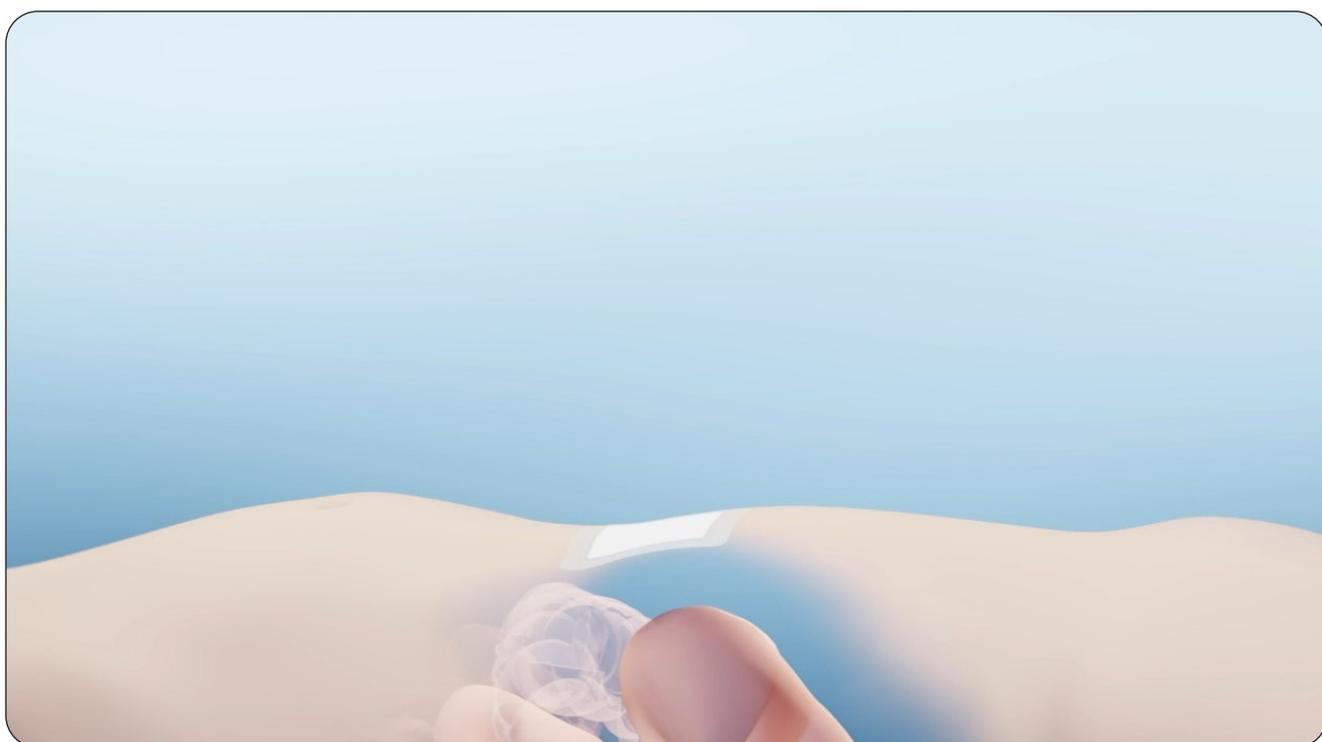


The liquid is completely withdrawn from the balloon.

Belly Button removal technique



The abdominal wall is stabilised by hand. The Freka Belly Button is carefully removed from the stoma with a gentle twisting motion.



Apply a plaster bandage to the stoma site until the stoma is completely closed.

Instructions for use: Freka Belly Button Comfort

Indications

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

Important information

The Freka Belly Button can be inserted with or without the use of the Seldinger method. The Seldinger method is 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).

Contraindications

- stoma not completely formed and healed
- length of stoma tract > 4.5 cm.

Important information

The Freka Belly Button 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 with malnutrition or being treated with steroids the stoma often takes longer than 4 weeks to heal completely.

Determination of the stoma length and selection of the Button

Important information

The length of the stoma tract must be determined before inserting a Freka Belly Button in order to select a suitable Button.

The FR size of the Button should correspond to the FR size(+/- 1 FR) of the feeding tube that is already in place.

- Insert the soft end of the Seldinger wire that has been provided into the lumen of the stomach through the cut off and endoscopically fixed PEG or through the feeding channel of the Button in situ.
- Withdraw the cut off PEG back into the stomach with the grasping forceps of the endoscope or remove the existing Button via the Seldinger wire following the manufacturer's instructions. Hold the Seldinger wire in the same position during this time.
- Place the stoma length measuring device over the Seldinger wire as per the manufacturer's instructions and carefully advance into the stomach. Then thread the length measuring device onto the outer end of the Seldinger wire in the stoma and advance into the stomach without altering the position of the wire in the stoma.

Instructions for use: Freka Belly Button Comfort

- Measure the stoma length according to the instructions for use for the length measuring device.
- The length of the stoma should be checked with the patient in supine and sitting position.
- Remove the length measuring device using the Seldinger wire as per the manufacturer's instructions. The position of the Seldinger wire must remain unchanged in the stoma.
- Select a Freka Belly Button to suit the stoma length required.
- Optimal is a Button length exceeding the maximal stoma length by 0.5 cm.

Important information

The Button must not under any circumstances be shorter than the stoma length because of the risk of pressure necrosis.

Checking the function of the Freka Belly Button

- Use the 5 mL luer slip syringe provided to draw the amount of sterile water as listed in the table below.
- Fill the balloon of the selected Freka Belly Button with the specified amount of fluid through the laterally mounted valve.
- Check the balloon visually for leaks. The filled balloon should be symmetrical. Do not press the balloon.

Button FR Size	Filling Volume (mL)
12 FR	3.0 mL
14 FR	4.0 mL
16 FR	5.0 mL
18 FR	5.0 mL
20 FR	8.0 mL
24 FR	8.0 mL

- Completely withdraw the fluid from the balloon using the same syringe, to make sure that the skin of the balloon lies tightly to the shaft. Store the filled syringe.

Important information

The balloon may only be filled with the amount stated. Overfilling impairs the life of the product.

- After checking its function, ensure that the balloon is completely empty. The skin at the balloon must lie as tightly as possible to the Button shaft to avoid injuries to the stoma during insertion.

Instructions for use: Freka Belly Button Comfort

Placement of the Freka Belly Button

The Freka Belly Button can be inserted without the use of the Seldinger method. The following should however be taken into consideration:

Important information

In patients who have formed fistulas or in whom a long, narrow or crooked stoma is suspected, particular care and use of the Seldinger method is strongly recommended to avoid complications. Under no circumstances may force be used to advance the stoma length measuring device and the Freka Belly Button. If you feel considerable resistance when advancing the tube, the Seldinger method may need to be used.

- Advance the introducer in the central opening of the Button (feeding port) so that the black markings on the handle and the opening lie on top of each other. The introducer is used to stiffen the shaft and to open the feeding valve for the Seldinger wire.
- For FR sizes ≤ 14 , the introducer for Seldinger technique contains no shaft due to the restricted internal lumen of the feeding channel. The introducer is only used to open the feeding valve for the Seldinger wire.
- The introducer without a shaft can be fixed by slightly pushing and twisting. For the placement without Seldinger technique the full introducer has to be used.
- Moisten the Button shaft with the lubricant provided.

Important information

Do not use paraffin oil or Vaseline as lubricant under any circumstances in order to avoid impairing the life of the product.

- Thread the Button with the introducer onto the outer end of the Seldinger wire in the stoma without altering the position of the wire in the stomach.
- Position the Button carefully, if necessary twisting slightly, intragastrically over the Seldinger wire until the head of the Button lies on the skin.
- Secure the Button manually. Fill the balloon with the specified amount of water by connecting the syringe to the lateral valve. Also take note of the filling volumes from the previous table.
- Now first carefully withdraw the Seldinger wire and then the introducer from the Button and seal it with the sealing tab.
- Clean and dry the stoma and the surrounding skin.

Important information

Do not fill the balloon with air. Filling with air impairs the life of the product.

Do not exceed the specified filling quantity of the balloon.

Check by endoscopy or x-ray that the button is in the correct position.

Instructions for use: Freka Belly Button Comfort

Feed administration and decompression

Nutrition may be administered immediately after the Freka Belly Button has been inserted.

Important information

The Freka Button Extension Set should always be used to open the central feed port in order to open the anti-reflux valve. Syringes should not be attached directly to the central opening as these can damage the anti-reflux valve.

- Open the sealing tab of the Button and advance the white connector from the Freka Button Extension Set into the central opening (feeding port). Make sure that the black markings on the connector and the opening lie on top of each other. Secure the adaptor in position by turning it 90° clockwise.
- When the administration of nutrition is finished, flush the Button with water. Slightly press the connector of the Freka Extension Set and turn it to the left or right until the black marking overlaps the marking of the Button opening.
- Remove the Freka Button Extension Set from the Button. Seal the central opening of the Button with the tab in feeding breaks.
- Flush the Freka Button Extension Set with warm water in feeding breaks.

Warning

Do not insert the connector of the Freka Button Extension Set into the balloon inflation port.

Freka Belly Button care

The Button must be flushed with 20 mL of lukewarm water before and after each feed or medicine administration or at least once a day.

Important information

Only medication designated for feeding tube administration can be administered.

- Do not use fluids containing acid, particularly fruit teas or fruit juices, when feeding enterally, as these can cause the feed to coagulate.
- In the event of a blockage, under no circumstances should an attempt be made to unblock the Button using high pressure (i.e. small volume syringe, e.g. 2 or 5 mL) or using an introducer. This poses the risk of perforation.
- Do not use paraffin oil or Vaseline for Freka Belly Button care.
- Always keep the outer surface of the Button and the skin around the entry site dry.
- Clean daily with warm water and mild antiseptic. Dry thoroughly.
- The Button should be rotated by 360° once a day to maintain freedom of movement within the stoma and to prevent skin irritation.
- Routinely check the entry site for redness, swelling and granulation tissue. If skin changes are noticed, consult the attending physician.

Instructions for use: Freka Belly Button Comfort

Important information

If the stoma leaks, or if there are hardened areas, pain or pressure around the stoma during and after feed administration, it is essential for a doctor to perform an examination.

If the Button becomes noticeably loose, the fill level of the balloon should be checked.

Checking the fill level of the balloon

- The fill level of the balloon should be checked once a week.
- Attach a luer slip syringe to the lateral valve of the Button and withdraw the water in the balloon completely.
- Hold the Button manually to prevent it slipping out of the stoma.
- Refill the balloon with the specified amount of sterile water. Also take note of the fill volumes from the previous table.
- If the fill volume is well below the limit, the seal of the lateral valve should be checked for leakage.
- The volume should be rechecked within 24 hours at the latest. If the fill volume is again below the limit, or leaks have occurred at the valve, the Button should be replaced.

Important information

If the Button is removed inadvertently, a doctor must be consulted immediately, as the stoma can close up quickly.

Administration of medicines

- Medicines should be administered in dissolved form via the Freka Button Extension Set. Preference should be given to medication in liquid form.
- Consult with a physician or pharmacist if a medication can be administered via a feeding tube.

Important information

The Button must be flushed with approx. 20 mL of water before and after any administration of medicines. Medicines and feed should never be mixed.

Medicines and feed must not be administered through the valve mounted on the side for balloon filling under any circumstances.

Duration of use

- The Freka Belly Button can remain in situ for several months. This may vary based on different factors e.g. the fill level of the balloon, the pH value in the stomach and daily care.
- Frequent administration of alcoholic drinks can cause material defects of the Button.
- Material defects caused by medicines are rare if the Button is flushed before and after each medicine administration.
- It is recommended that the Freka Belly Button always be replaced by specialists and medically trained personnel.

Instructions for use: Freka Belly Button Comfort

How to remove the Freka Belly Button

- Attach a 10 mL luer syringe to the laterally mounted valve of the Button and completely empty the balloon by aspirating the fluid.
- Carefully withdraw the Button from the stoma. Hold the abdomen whilst doing so.
- Apply an adhesive dressing. A fasting period is not necessary.
- Medical supervision is recommended until the stoma is completely healed.

Ordering information

FR size / Shaft length	12 FR	14 FR	16 FR	18 FR	20 FR	24 FR
1.0 cm	7751363	7751373	7751383	7751394	7751405	7751416
1.5 cm	7751364	7751374	7751384	7751395	7751406	7751417
2.0 cm	7751365	7751375	7751385	7751396	7751407	7751418
2.5 cm	7751366	7751376	7751386	7751397	7751408	7751419
3.0 cm	7751367	7751377	7751387	7751398	7751409	7751420
3.5 cm	7751368	7751378	7751388	7751399	7751410	7751422
4.0 cm	7751369	7751379	7751389	7751400	7751413	7751423
4.5 cm	7751370	7751380	7751390	7751403	7751414	7751424
5.0 cm	7751372	7751382	7751393	7751404	7751415	7751425

	Packaging	Art.No.
Freka Button Extension Set 1, 30 cm, angled, ENFit	10 x 1	7981397
Freka Button Extension Set 2, 30 cm, straight, ENFit	10 x 1	7981398
Stoma length measuring device for stoma 14 FR and above	10 x 1	7750921

