



FLOCARE® PEG SET

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FLOCARE® PEG SET

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KIT PEG

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PEG

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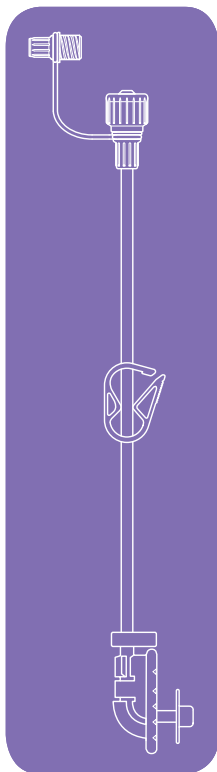
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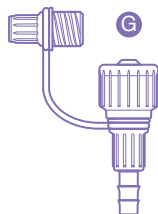
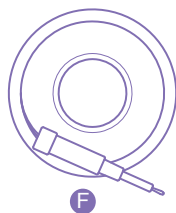
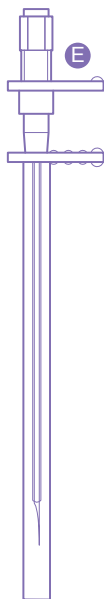
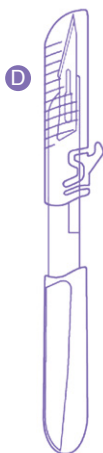
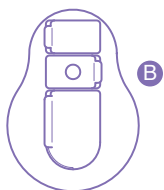
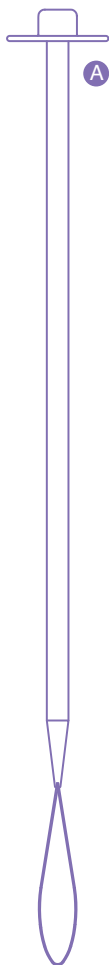
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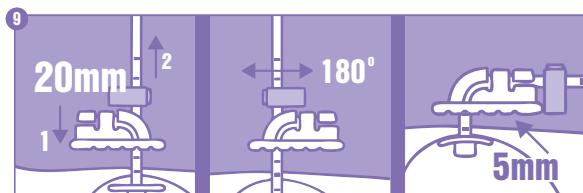
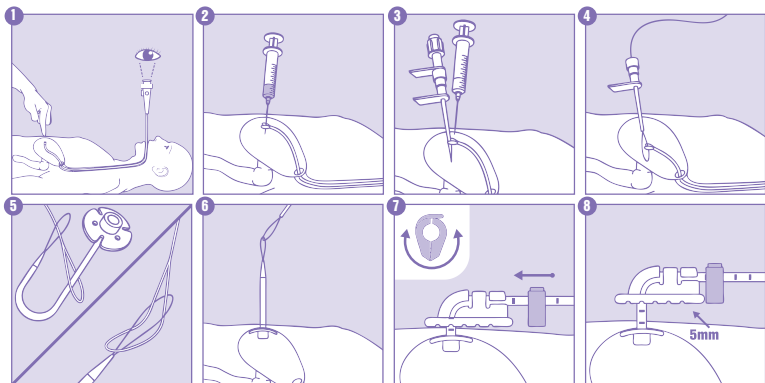
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PRODUCT DESCRIPTION

The Flocare PEG set is a percutaneous endoscopic gastrostomy set intended for patients requiring long term intragastric administration of tube feeding. The Flocare PEG is intended to be placed using the 'pull' technique, under endoscopic control. The PEG Summary of Safety and Clinical Performance (SSCP) can be found in EUDAMED at <https://ec.europa.eu/tools/eudamed>, or provided upon request.

CONTENTS

A clear polyurethane tube (A), 40 cm in length, with

- 3 radio - opaque lines
- A three - winged silicone internal retention disc
- A Hydromer® coated tip with loop, to facilitate passage through the abdominal wall
- Cm markings up to 12 cm from the internal disc

INTENDED USE

The intended use of the Flocare PEG sets is to facilitate the delivery of enteral nutrition in patients requiring long-term tube feeding.

Flocare Percutaneous Endoscopic Gastrostomy (PEG) tube is intended to provide long-term access to the stomach for the delivery of enteral nutrition or liquids, directly into the stomach (intragastric feeding), in patients who are unable to meet their nutritional requirements through oral intake, but whose gastrointestinal tract is functional. A PEG is intended for use when long term (> 6 weeks) tube feeding is expected.

INDICATIONS

- Long - term intragastric tube feeding (with gastric motility) in patients with inadequate oral nutritional intake who require prolonged tube feeding support and hydration
- Gastric decompression, when clinically indicated

INTENDED TARGET GROUPS/PATIENT POPULATION

The Flocare PEG set is intended for enteral tube feeding in adult patients. Due to the dimensions of the internal retention disc, it is not intended for use in infants and young children. Use in selected paediatric patients may be considered based on the clinical judgement of qualified healthcare professionals, considering the compatibility of the patient's oesophageal anatomy, body size, clinical condition and intended use.

INTENDED USERS AND QUALIFICATIONS

The set-up and placement of the Flocare PEG set must be performed by trained and qualified healthcare professionals.

Daily use, care and maintenance of the Flocare PEG may be carried out by a trained patient or caregiver under medical supervision.

CLINICAL BENEFITS

The use of the Flocare PEG set enables long-term access to the gastrointestinal tract for the delivery of enteral nutrition in patients who are unable to meet their nutritional requirements via oral intake. Its use supports the maintenance and improvement of nutritional intake and hydration in eligible patients.

CONTRAINDICATIONS

- Mechanical obstruction of the GI tract (unless the tube placement is indicated for stomach decompression)
- Severe coagulation disorders
- Severe ascites &/or gastritis
- Ileus
- Anorexia nervosa
- Severe psychosis
- Advanced dementia
- Acute pancreatitis & peritonitis
- When it is impossible to bring the anterior part of the stomach against the abdominal wall (subtotal gastrectomy, ascites, hepatomegaly, etc.)
- Interposed organs, e.g. liver, colon
- Marked peritoneal carcinomatosis
- Tumor infiltration at puncture site
- Oesophageal stenosis
- Gastrointestinal tract bleeding

Notice: any serious incident that has occurred in relation to this device is to be reported to Nutricia and the local competent authority

PEG PLACEMENT

Preparation prior to endoscopic placement via Pull technique of Flocare PEG tube:

PEG tube placement is only to be executed by trained and qualified healthcare professionals.

The PEG tube insertion is performed with the patient in a supine position. The patient is prepared as usual for endoscopy. Thorough oral and pharyngeal hygiene is very important. Administration of a prophylactic antibiotic should be considered. If possible, explain the procedure to the patient.

In addition to the Flocare PEG set, the following equipment is required:

- Flexible endoscope with biopsy forceps
- Sterile gauze
- Skin disinfectant
- Syringe with local anaesthetic and long IntraMusculaire needle (IM)

PEG tube Placement:

1. Normally, PEG tube placement is executed under mild sedation. If this is not the case, a topical anaesthetic of the vocal cords has to be considered. Pass the endoscope into the stomach and inflate the stomach. With the room lights dimmed, locate the appropriate puncture site in the left upper quadrant of the stomach, by placing a finger at the point of maximum transillumination by the endoscope light (fig.1). Palpate the abdominal wall to ensure the colon is not obstructing access to the stomach.
2. Clean the entire abdominal wall with a disinfectant and put sterile drapes around the puncture site. With the long IM needle, inject a local anaesthetic into the skin and in all layers of the abdominal wall. Insert the IM needle into the cavity of the stomach. Keep the IM needle in place by grasping it with the biopsy forceps. This avoids the stomach wall from dislocating versus the abdominal wall. (fig.2)
3. To open the scalpel, push the lever at the top of the scalpel down and slide the cover backward, exposing the blade. With the scalpel, make an incision of $\pm 4 - 5$ mm in length very close to the IM needle. To close the scalpel, push the lever at the top of the scalpel down and slide the cover forward, protecting the blade.
Push the puncture needle with the trocar through the incision into the stomach cavity (fig.3). Open the biopsy forceps, remove the IM needle and grasp the trocar with the forceps.
4. Remove the puncture needle and leave the trocar in place. Insert the pull wire through the trocar and grasp the wire with the biopsy forceps. (fig.4)
5. Dip the dilation tip of the tube in sterile water for approx. 10 seconds to activate the Hydromer® coated tip. Pass the loop of the wire through the dilation loop, over the internal retention disc and pull snugly. (fig.5)
6. Pull the wire exiting the abdomen. The tube is then pulled down through the mouth into the stomach cavity and pulled out through the abdominal wall, using the dilation tip to dilate the exit site. The Hydromer® coating on the dilation tip will facilitate this. Remove the trocar when the conical tip of the tube is locked in the intragastric end of the trocar. Pull the internal retention disc of the tube snugly against the stomach wall (fig.6).
7. Cut the tube below the conical part. Slide the external retention disc (C) over the tube. Secure it in position by passing the tube through the disc.
Keep the external retention disc positioned slightly away from the skin, without applying tension, for the initial 24 hours. During this period, avoid applying traction to the external retention disc and the safety clamp (if present). Maintain the correct position of the external retention disc by placing the blue safety clamp (if present) immediately behind the disc (Fig.7). Place the quick release clamp onto the tube. Submerge the shaft of the ENFit feeding connector (G) in water and insert the shaft fully into the tube. Confirm the tube position endoscopically or by X-ray.
8. Record the brand name, the Charriere, the batch/LOT information and the introduced length of the PEG into the patients' medical records. Ensure that the enclosed PEG implant card and UDI card are completed and provided to the patient.

MAINTENANCE AND AFTERCARE

AFTERCARE POST ENDOSCOPIC PLACEMENT OF FLOCARE PEG SET:

- Feeding initiation: Tube feeding may be initiated within 4 hours after uncomplicated PEG placement. Start feeding gradually and monitor the patient. If intolerance or adverse signs occur, pause feeding and assess according to local clinical protocols.
- Until the stoma tract is formed and the incision is healed, the PEG exit site should be daily monitored and cleansed with, for instance, 0.9% w/v sodium chloride, sterile water or freshly boiled and cooled water, and dry by using aseptic wound care.
- Allow a distance of approximately 5 mm (fig. 8) between the external retention disc and the skin, to place a sterile Y dressing (that does not shed fibers) under the external retention disc.

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- When the dressing is placed under the external retention disc, tension has to be avoided. Occlusive dressings should be avoided.
- Renewal of the sterile Y-compress is recommended on a daily basis for the first 7 days, or any later as required, after placement as keeping the stoma site dry is important for stoma healing.

MAINTENANCE OF FLOCARE PEG SET AFTER A HEALED STOMA SITE:

- After stoma healing, dressings can be omitted or reduced to one or two times a week depending on medical instructions. The entry site can be cleansed using soap and water of drinking quality. Rinse and dry the skin thoroughly.
- Release the tube out of the external retention disc, rotate the tube daily by 180° around its axis. After mobilization, return the tube to its initial position with some free distance (5 mm) between the skin and the external retention disc. (fig.9)
- At least, once a week, move the tube inwards (move up and down in the stoma) (at least 2 cm) (Fig 9). After mobilization, return the tube to its initial position with some free distance (5 mm) between the skin and the external retention disc. (fig.9)
- If present, always keep the blue safety clamp in place, including during wound care, to ensure that the tubing is repositioned correctly after wound care. The cm markings may also be used.
- Check the position of the Flocare PEG by confirming the position of the external retention disc. The cm markings may also be used. Perform this check each time the feed container is changed. If possible and if there is any doubt regarding the position of the tube measure the pH of aspirated gastric content. A pH value below 5.5 confirms correct position of the tube in the stomach.
- Appropriate ancillaries, including enteral extension sets, giving sets and syringes, should be used using ENFit (enteral) connectors of a recognized standard (ISO80369-3) in order to avoid misconnection errors.
- The PEG System should be inspected daily for its condition. Regular checks for signs of degradation (e.g. cracks, delamination, disassembly) are required. If any damage is identified, replace the affected components with new spare parts, if applicable.
- Regular monitoring by a qualified healthcare professional is recommended.

WARNINGS

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- Any significant change to the PEG (discoloration, hairline cracks, leakage, etc.) should be reported to a qualified healthcare professional.
 - Always keep the blue safety clamp in place (if present).
 - Disinfectants such as Povidone - Iodine (PVP - I; e.g.: Iso - Betadine®, Braunol®) and Octenidindihydrochlorid - Phenoxyethanol (e.g.: Octenisept®) should not be used because repeated exposure to this disinfectant might negatively affect the physical/mechanical properties of the tube. It is recommended to use disinfectants based on Polyhexanid (e.g. Prontosan, Prontosan C.), based on Octenidine (e.g. Octennilin) or ActiMaris disinfectants wound irrigation solutions.
 - The Flocare PEG connector CH10 has a metal connection pin for fixation in the PEG tube - do not expose the PEG CH10 with the CH10 ENFit connector attached to areas of strong magnetic fields, e.g. MRI equipment.
 - There are no incompatibilities known in the choice of substances administered via the PEG. Precaution is to be in place in delivering via the PEG, as unknown effects can occur. After any administration delivery, the PEG is to be flushed with water.
 - Material defects and tube occlusion can be largely ruled out if the Flocare PEG Set is adequately flushed before and after every administration of nutrition and/or medication.

- Avoid using acidic substances such as cranberry juice and cola beverages to flush feeding tubes as the acidic quality when combined with formula proteins may actually contribute to tube clogging.
- The PEG has not been tested for use with medication. If alternative routes of drug delivery are not an option, the pharmacist or other knowledgeable healthcare professional needs to give authorization for medicines to be given in conjunction with enteral feeding and provide guidance on the preparation & administration to ensure safe use.

POTENTIAL COMPLICATIONS

Potential complications include , but may not be limited to :

- Peristomal wound infection
- Pain at the insertion site
- Tube occlusion or blockage (including clogging, kinking or obstruction)
- Tube Dislodgment
- Leakage from tube or the tube connection due to wear, porosity, fracture or insufficient connection
- Peristomal cellulitis
- Peristomal bleeding
- Skin irritation, Eczema, dermatitis or hypergranulation tissue
- Aspiration Pneumonia
- Buried bumper syndrome
- Colon puncture, injuries or perforation of intra-abdominal organs during the placement procedure
- Laceration of the gastric or small bowel mucosa , and stridor during the placement procedure
- Tumor tract seeding during the placement procedure
- Abdominal hemorrhage
- Peritonitis
- Abscess formation
- Granuloma formation
- Ileus
- Necrotizing fasciitis
- Pneumoperitoneum
- Gastric Ulcer
- Gastric outlet obstruction
- Site herniation
- Gastrocutaneous fistula

The occurrence of many of these potential complications depends on the quality of aftercare given to the tubing system and may be reduced when appropriate care and maintenance measures are followed (see the "Maintenance and aftercare" paragraph for further information).

For any suspected complications, consult a qualified healthcare professional.

GENERAL FLUSHING AND SYRINGE USE POLICY

Routinely flush the tube with water before and after the administration of feed or medication and at least every 8 hours to prevent blockage of the tube.

- As practicable, use an enteral syringe (minimum size of 20mL) for flushing the tube and always flush in a controlled manner.
- For medication administration directly into the tube, always administer using an appropriate size enteral syringe for the volume of medication but ensure delivery is in a controlled manner. In case more than one medication is administered at one time; make sure the tube is flushed thoroughly between types.
- Never use excessive force. If there is any resistance, stop the procedure and consult your clinician.

DURATION OF USE

The tube is intended to provide long-term (>3 months) intragastric access for enteral tube feeding. The durability of the PEG tube system is primarily linked to the clinical use setting, its careful handling and may vary depending on several factors, including medication use, gastric PH, gastric motility, patient mobility and tube care. The following spare parts are available and may contribute to maintaining the functionality of the Flocare PEG system: External retention disc, quick release clamp, blue safety clamp and the ENFit feeding connector. Routine proactive replacement of the PEG tube at fixed intervals is not required. In case of doubt regarding the position or condition of the internal retention element or the functionality of the PEG, an endoscopic evaluation of the tube should be performed, as clinically indicated.

REMOVAL OR REPLACEMENT

- The tube should not be removed within 10 days of placement, or until the stoma tract is formed.
- Removal of this tube depends upon the viability of the product and/or should be performed under medical instruction.
- To remove the tube, cut it at skin level. The internal retention disc and the remaining tube must be retrieved by endoscope. After use, dispose of product and packaging in accordance with hospital, administrative and/or local policy.
- In patients for whom endoscopic removal is no longer feasible or is not clinically indicated, the PEG tube may be cut at skin level, allowing the internal retention disc to pass naturally through the gastrointestinal tract. This removal method is associated with an increased risk of complications, including bowel obstruction. Close clinical follow-up and careful monitoring of the patient are required. This method is contraindicated in paediatric patients and in patients with a history of abdominal surgery.
- In case of PEG tubing breakage or occlusion, the PEG must be removed and can be replaced with an alternative feeding device if clinically indicated. In case of any tube degradation based on the judgement of a qualified healthcare professional, removal and replacement with an alternative feeding device may be performed.
- The Flocare PEG can be replaced by a replacement gastrostomy tube (Gastrostomy tube or Button).
- Oral feeding after PEG removal may only start after medical approval.

SINGLE PATIENT USE

Do not reuse, reprocess or re-sterilize this device. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.